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STATE OF NEVADA

AGENCY FOR NUCLEAR PROJECTS

NUCLEAR WASTE PROJECT OFFICE

COMPLIANCE DEMONSTRATION REPORT

NWPO QUALITY ASSURANCE PROGRAM AND IMPLEMENTING PROCEDURES

COMPLIANCE WITH

NRC REVIEW PLAN ACCEPTANCE CRITERIA

AND

RELATED DOCUMENTS

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Introduction and Purpose

In response to the United States Department of Energy's (DOE's) selection of Yucca Mountain, Nevada as a potential site for a high-level nuclear waste repository the State of Nevada will be conducting investigations of the impact of any such repository on the public health, safety and environment. The investigations are being performed by the Agency for Nuclear Projects/Nuclear Waste Project Office (NWPO) and its contractors and subcontractors. In broad terms NWPO's investigative activities consist of (1) monitoring (surveillance) of the DOE's site characterization activities, (2) critical review and analysis of characterization data and analyses from DOE and other sources and (3) independent investigations as needed to (a) appraise DOE data, assumptions, conclusions and designs and (b) to establish NWPO's own data bases and interpretation techniques.

NWPO appreciates the necessity of quality assurance (QA) in activities under its sponsorship. To establish the credibility of its technical program NWPO management has instituted a QA program and implementing procedures to ensure that activities of NWPO and its contractors, subcontractors, and vendors/suppliers, working as an integrated team, will be in compliance with applicable QA requirements. The QA program is part of a six-volume NWPO QA Manual. Volume 1 contains, in addition to the QA program, the QA procedures, Statement of Quality Assurance Policy, and a Glossary. Volumes 2 through 6 contain technical procedures.

The program and procedures have been written to comply, insofar as possible, with acceptance criteria of the United States Nuclear Regulatory Commission's (NRC's) "NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories," Appendix A, June 1984, and with applicable requirements of other documents listed in the References Section, herein. The review plan is the NRC's adaptation of 10CFR50, Appendix B to repository facilities and has been chosen by NWPO

because its criteria are the closest to NWPO's requirements of any existing set of criteria. NWPO's program and procedures do not adhere to acceptance criteria or to other requirements when they deviate from or do not apply to NWPO's objectives, intentions, strategy, or circumstances. Neither NWPO nor its contractors, or subcontractors design nuclear power plants or nuclear waste repository systems nor do they perform site characterization activities. Rather, they are concerned with activities related to acquisition and analysis of data that the DOE may or should use as a basis for any repository design it may choose to propose or for any feasibility decisions it may choose to make. Further, NWPO's project organization is small and simple compared to that of the DOE. NWPO operates primarily through contractors who are included in NWPO's QA Program and procedures rather than through contractors who have their own QA programs. See the Conclusions Section, herein, for a list of NRC acceptance criteria that contain elements not addressed or modified to some degree in NWPO's QA Program and implementing procedures.

Taking into account all of the foregoing the purpose of this report is to demonstrate how NWPO's QA Program and implementing procedures comply with NRC acceptance criteria and other listed criteria, where they are relevant to NWPO's objectives, strategies, and circumstances, and to explain modifications and deviations from these criteria where the criteria are not relevant to NWPO's needs.

References

1. U. S. NRC, "NRC Review Plan: Quality Assurance Programs Requirements for Site Characterization of High Level Nuclear Waste Repositories," June 1984

2. U. S. NRC, NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management," June 1983

3. U. S. NRC NUREG-1297, "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories," February 1988

4. 10CFR50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," 1975

5. 10CFR60, Subpart G, "Disposal of High-Level Radioactive Waste in Geologic Repositories, Quality Assurance," 1983

6. ANSI/ASME NQA-1-1986 Edition, "Quality Assurance Program Requirements for Nuclear Facilities"

7. U. S. NRC NUREG-1298, "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories," February 1988

Demonstration of Compliance

General Statement

This section of the report is organized around Appendix A of the NRC's acceptance criteria (NRC Review Plan) which is divided into 18 sections, and numerous subsections, each section corresponding to a criterion of 10CFR50, Appendix B. Each NRC acceptance criterion subsection is quoted verbatim and addressed, separately, immediately below. Criteria of other documents listed in the References Section are included and addressed at appropriate places in the report.

In general, NWPO's QA Program is divided into 18 sections corresponding to criteria in the NRC Review Plan. There is, however, an introductory section (Section 00) that describes the organization of the NWPO QA Manual, that states NWPO's objectives, that indicates the purpose of the QA program, that commits NWPO and its contractors, subcontractors, and vendors/suppliers to NWPO's QA Program, and that commits NWPO to relevant requirements of listed master documents. Some of the subcriteria of the NRC Review Plan are addressed in more than one section of the QA program or in sections that do not correspond to the particular subcriterion number. This is indicated by appropriate cross-references in the compliance responses.

Section 01 -Organization

"1. The Organization elements responsible for the QA program are acceptable to the NRC staff if:

1.1 The responsibility for the overall program is retained and exercised by the DOE* at a level which is commensurate with the level of the DOE official who will submit the license application. While the line organization is responsible for performing quality affecting activities properly, the QA organization** shall verify the proper performance of work through implementation of appropriate QA controls."

Compliance Response

This subcriterion is not entirely applicable to NWPO's activities because NWPO does not submit license applications. As indicated on page 01-1 of NWPO's QA Program,*** second paragraph, "Overall responsibility for... the State's... QA policies is exercised by NWPO's Executive Director." Responsibility of the line organization (i.e., contractors, subcontractors, or NWPO's Division of Technical Programs) is indicated on Figures 01-1 through 01-5 and on page 01-8 of the program, first paragraph, which states, "...NWPO's Division of Technical Programs (Administrator of Technical Programs) and the Project Managers, Principal Investigators, Laboratory Directors, and other persons are

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* Throughout the report, all NRC criteria references to the DOE are interpreted as if they were references to NWPO.

** Unless otherwise indicated the QA Manager is the QA organization. On occasion Technical Auditors are included in the QA organization.

***All references to the QA Program, QA procedures (QAPs), Statement of QA Policy, or to the Glossary are references to Revision 0, June 10, 1988, as contained in Volume 1 of the NWPO QA Manual.

responsible for the quality of work..." See, also, page 01-1, third paragraph, "... The Principal Investigators perform... technical tasks ... with the aid of associate investigators, support staff, subcontractors, and vendors/suppliers ..."

Responsibility of the QA organization to verify proper performance of work through the QA program is indicated on page 01-8 of the program, second paragraph and 01-9, first paragraph, which state that, "The QA Manager has the responsibility and authority to... perform audits of NWPO's and its contractors', subcontractors', and vendors'/suppliers' activities ..." (item 6). See, also, page 01-7, fourth paragraph, "... NWPO is responsible for quality assurance... (and) for review and audit of NWPO's, and contractors'/subcontractors' activities ..."

The QA Manager's verification responsibilities are indicated throughout the program and procedures. See, for example, Sections 16 and 18 of the program and procedures QAP-15.1, "Nonconformances," QAP-16.1, "Corrective Action" and QAP-18.1, "Audits." "...As needed... Technical Auditors may use technical verification of work or other means to confirm effectiveness of revision/verification and quality of work," (page 18-2 of the program, first paragraph).

"1.2 DOE describes major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations."

Compliance Response

NWPO retained an outside consultant to prepare its initial QA program and QA procedures and may retain outside consultants to help with the annual management

assessment of NWPO's QA Program (page 02-4 of the program, first paragraph, and procedure QAP-2.4) but otherwise NWPO does not delegate any responsibility for establishing and implementing the QA program. This is indicated on page 01-7 of the program, second paragraph, "The QA Manager is responsible for the QA program and procedures..." and in the fourth paragraph, "...NWPO is responsible for quality assurance..." Also, see page 01-8 on which the QA Manager is given the responsibility and authority "...to approve the QA manual, prepare and/or approve changes thereto, and interpretations thereof ..." (item 2). Refer, also, to page 02-1, first paragraph, which states that, "The... (NWPO)... program is the sole QA program governing activities of NWPO and its contractors/subcontractors and vendors/suppliers working as an integrated team" and to page 00-1 of the program, third paragraph, "There are no separate contractor or subcontractor QA manuals that govern NWPO-sponsored activities," and to page 18-1, first paragraph, "...There are no contractors', sub-contractors' or vendors'/suppliers' audit organizations that audit NWPO-sponsored activities..."

As indicated on page 02-2, first paragraph, and in procedure QAP-2.2, "Preparation and Control of Technical Procedures," Subsection 4.1, contractors and subcontractors are responsible for preparation of their own technical procedures. However, the QA Manager and Administrator of Technical Programs review and approve these technical procedures (QA program, page 02-1, second paragraph, page 02-2, first paragraph, and procedure QAP-2.2, Subsection 4.15).

"1.3 DOE describes how responsibility is exercised for the overall QA program. The extent of management responsibility and authority from DOE headquarters and from the field office should be addressed."

Compliance Response

As indicated on page 01-7 of the program, first paragraph, "...The QA Manager is responsible for the QA program and procedures..." Details of how his/her responsibility is exercised are provided on page 01-8, third paragraph, 01-9, first paragraph, and throughout the QA program and procedures. For example, "...audits are performed by the QA Manager... with the aid of qualified independent Technical Auditors, as needed..." (page 18-1 of the program, first paragraph) and "...Technical Auditors may use technical verification... or other means to confirm effectiveness of verification/review and quality of work..." (page 18-2, first paragraph).

The headquarters/field office relationship implied by this subsection is not applicable to NWPO's organization nor to NWPO-sponsored activities.

"1.4 DOE evaluates the performance of work delegated to other organizations. This shall include audits of the prime contractor's* QA program and audits of representative subcontractors, consultants, vendors, and laboratories furnishing equipment or services to the prime contractor or DOE. The frequency and method of evaluation should be specified."

(*"Contractor" as used in this Appendix refers to all contractors, subcontractors, vendors, consultants, or agents performing work covered by the quality assurance program.)"

Compliance Response

As indicated in the Glossary of Definitions the NWPO QA Program uses "contractor" to indicate an organization furnishing services to NWPO and "subcontractor" to indicate an organization furnishing services to a contractor. The terms "vendor" and "supplier" are synonymous and both signify an organization furnishing materials, equipment, apparatus, or instruments to NWPO, to a contractor, or to a subcontractor.

In the broadest sense NWPO evaluates performance of other organizations by requiring them to report on their activities (see, for example, procedure QAP-3.2, "Technical Reports," Subsection 5.1, and procedure QAP-3.3, "Peer Reviews," Subsection 4.7). In addition, "...NWPO reviews contractor surveillance reports of contractor/subcontractor activities... (and)... may also conduct its own surveillances of contractor and subcontractor activities..." (QA program, page 07-1, first paragraph).

With reference to audits of work delegated to other organizations page 01-7 of the QA program, fourth paragraph, indicates that, "NWPO is responsible... for review and audit of... contractors'/subcontractors' activities..." See, also, page 18-2, first paragraph, outlining the scope of technical audits performed by Technical Auditors. As stated on page 18-1, second paragraph, "...Quality of work audited is a major audit goal..."

NWPO does not audit contractors' QA programs because the program precludes separate contractor QA programs or QA manuals for NWPO-sponsored activities (see page 00-1, third paragraph and page 02-1, first paragraph). As indicated on page 07-1, second paragraph, of the program and on page 01-9, first paragraph, item 6, NWPO audits contractors, subcontractors, and vendors/suppliers furnishing equipment or services. Specific audit responsibilities (i.e., frequency and method) are detailed in procedures. QA procedure QAP-18.1, "Audits," specifies that audits be scheduled at frequencies commensurate with the nature, status, and expected duration of the activity being audited and also provides for special audits (Subsection 4.1). Audit methods are addressed in detail in the same procedure (e.g., Subsections 4.5 and 4.9). See, also, page 18-1, of the QA program, second paragraph and page 18-2, first, second and third paragraphs.

"1.5 Qualified individual(s) or organization element(s) are identified within DOE's organization as responsible for the quality of the delegated work prior to initiation of activities."

Compliance Response

In a general sense, quality of work within the scope of the QA program is the responsibility of the QA Manager and of the Administrator of Technical Programs. This is shown on page 01-7 of the program, second paragraph, "...The QA Manager is responsible for the QA program and procedures..." and on page 01-1, second paragraph, which states, "...the Administrator of Technical Programs... is responsible for NWPO contractor(s) and

subcontractor(s) performing activities within the scope of the QA program." These responsibilities are an integral part of the QA program and all contractors, subcontractors, and vendors/suppliers must agree to adhere to the program as part of their contracts (page 04-2 of the program, item 3a). See responses to Subcriteria 1.1, 1.3, and 1.4 above for additional background on this topic.

"1.6 Clear management controls and effective lines of communication exist for QA activities between DOE and its contractors, to assure direction of the QA program."

Compliance Response

As indicated on page 01-8 of the QA program, third paragraph, "The QA Manager has the responsibility and authority... to communicate directly with the Executive Director... the Project Managers, and the Principal Investigators and also with the peer reviewers, if any..." Also, the QA Manager reports directly to the Executive Director (page 01-7, second paragraph). The Administrator of Technical Programs, who also reports to the Executive Director, is responsible for and coordinates contractor/subcontractor activities through the Project Managers (page 01-1, second paragraph). See, too, Figure 01-1 on page 01-2 of the program.

Another vehicle of management control is the requirement that, "...contractor and subcontractor activities... must be authorized and controlled by QA and/or technical procedures..." (page 02-2 of the program, third paragraph) that, "...The QA Manager... reviews and approves all technical procedures..."

(page 02-2, first paragraph) and that, "...the... Administrator of Technical Programs approves... (contractor-generated)... technical... procedures..." (page 02-2, first paragraph; see, also, procedure QAP-2.2, Subsection 4.15).

"1.7 Organization charts clearly identify all the 'onsite' and 'offsite' organizational elements which function under the cognizance of the QA program and the lines of responsibility."

Compliance Response

The terms "onsite" and "offsite" are not directly applicable to NWPO's and its contractors' and subcontractors' organizations. There are no "onsite" and "offsite" organizations as understood by the NRC Review Plan although field activities may be conducted from time to time. Figures 01-1 through 01-5 (pages 01-2 through 01-6 of the program) are organization charts that identify organizational elements that function under the cognizance of the QA program and that show lines of responsibility. "...As illustrated by the charts, there is a close integration of NWPO, contractor and subcontractor activities under the control of NWPO..." (page 01-1 of the program, first paragraph). This applies to all activities wherever and by whomever performed.

"1.8 The QA organization is involved in the aspects of the high level waste repository program that affect safety and waste isolation. The extent of QA controls is determined by the QA staff in combination with the line staff and is dependent upon the specific activity, its complexity, and its importance to safety or waste isolation as defined in 10 CFR Part 60.2."

Compliance Response

As appropriate, the QA Manager is involved in all activities essential to NWPO's goals (the... "QA Manager is responsible for the QA program and procedures..." (page 01-7 of the program, second paragraph) and "The program has been written to control activities essential to attainment of NWPO's objectives..." (page 02-1, first paragraph)).

The QA Manager's "...responsibilities are detailed in implementing procedures" (page 01-8 of the program, third paragraph), not in combination with the line staff (contractors). As indicated on page 00-1, second paragraph, NWPO has its own objectives, not necessarily those of the DOE. NWPO considers all NWPO-sponsored activities equally significant for purposes of QA control. Contractors'/subcontractors' obligations are defined by the QA program, by implementing QA and technical procedures, and by procurement contract documents (page 01-7 of the program, fourth paragraph and page 01-8, first and second paragraphs) and the QA Manager uses audits and other means to impose whatever degree of QA control is needed to assure the quality of any particular activity or item.

The foregoing points are illustrated as follows:

"...contractor and subcontractor activities that NWPO considers significant to its objectives must be... controlled by QA and/or by technical procedures and... by procurement contract documents..." (page 02-2 of the program, third paragraph). "The QA Manager approves all QA and reviews and approves all technical

procedures..." (page 02-2, first paragraph). "The QA Manager has the... authority to... review and concur with procurement contract documents..." (page 01-8, third paragraph and page 09-1, first paragraph). "All significant aspects of the program and all participating organizations and their activities are audited." (page 18-2, first paragraph). "All audits are performed by the QA Manager... with the aid of...Technical Auditors, as needed." (page 18-1, first paragraph). "Scheduling and timing of audits depends on the nature and duration of the activity being audited." (page 18-2, first paragraph).

See responses to Subcriteria 2.1 and 2.5 below.

"1.9 DOE and its prime contractor describe the QA responsibilities of each of the organization elements noted on the organization charts."

Compliance Response

In the sense of a separate QA organization performing audits and other functions, NWPO exercises all QA responsibilities. "There are no separate contractor or subcontractor QA manuals that govern NWPO-sponsored activities," (page 00-1 of the program, third paragraph). "There are no contractors', subcontractors', or vendors'/suppliers' audit organizations that audit NWPO-sponsored activities." (page 18-1, first paragraph). "Overall responsibility... for implementation of the State's... QA policies is exercised by NWPO's Executive Director." (page 01-1, second paragraph). "The QA Manager is responsible for the QA program and procedures..." (page 01-7, second paragraph). "...NWPO is responsible for quality assurance..." (page 01-7, fourth paragraph).

As indicated in the statement of Quality Assurance Policy (page 1, second paragraph and page 2, first paragraph) contractors', subcontractors' and NWPO technical personnel's QA responsibilities are to comply with NWPO's QA Program and Procedures in their work. Detailed responsibilities are indicated throughout the program and procedures.

QA responsibilities of NWPO's QA organization are summarized on page 01-8 of the program, third paragraph; page 09-1, first paragraph, and throughout the program and procedures.

"1.10 DOE and its prime contractor identify a management position within each respective organization that retains overall authority and responsibility for the QA program. This position, occupied by an individual with appropriate management and QA knowledge and experience has the following characteristics:

a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design, engineering, site investigations, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.

b. Has effective communication channels with other senior management positions.

c. Has responsibility for approval of QA Manual(s), changes thereto, and interpretations thereof.

d. Has no other duties or responsibilities unrelated to QA that would prevent full attention to QA matters."

Compliance Response

With reference to Subcriterion 1.10 in general, NWPO's "... QA Manager is responsible for the QA program and procedures..." (page 01-7 of the program, second paragraph). As indicated by the list of requirements on page 01-9 the QA Manager must be a person with appropriate QA knowledge, experience and management expertise. There is no corresponding position in the contractors' or subcontractors' organizations because they are included in NWPO's program ("There are no separate contractor or subcontractor QA manuals that govern NWPO-sponsored activities." (page 00-1 of the program, third paragraph)). See, also, the response to Subcriterion 1.9 above.

With reference to Subcriterion 1.10a, "The QA Manager... reports directly to the Executive Director. The QA Manager devotes his/her time exclusively to quality assurance functions." (page 01-7 of the program, second paragraph). The Executive Director is at the highest level of NWPO management (page 01-1, second paragraph). See Figure 01-1, page 01-2, in the QA program.

Subcriteria 1.10b and c are addressed in items 1 and 2 on page 01-8 of the QA program. "The QA Manager has the authority and responsibility to: 1. communicate directly with the Executive Director, the Administrator of Technical Programs, the Project Managers, and the Principal Investigators ... 2. (to) approve the QA Manual, prepare and/or approve changes thereto, and interpretations thereof..." Further, in his/her capacity as Lead Auditor the QA Manager in effect interprets the program and procedures.

Subcriterion 1.10d is addressed on page 01-7 of the program, second paragraph, "The QA Manager devotes his/her time exclusively to quality assurance functions."

"1.11 Verification of conformance to established requirements is accomplished by individuals or groups within the QA organization. Certain exceptions for: design, item 3.7; inspections, item 10.2; and test data evaluation, item 11.3 are outlined in these sections."

Compliance Response

The QA Manager, by means of audits and with the aid of Technical Auditors, as needed, verifies conformance to established requirements of all activities essential to attainment of NWPO's objectives. As indicated on page 01-9 of the program the QA Manager is responsible for performing audits. As indicated on page 18-1 of the program, first paragraph, "All audits are performed by the QA Manager in accordance with procedure QAP-18.1, with the aid of qualified independent Technical Auditors as needed..." As indicated on page 18-2 of the program, first paragraph, "All significant activities... are audited... Technical Auditors may use technical verification of work or other means to confirm effectiveness of revision/verification and quality of work."

Items (Subcriteria) 3.7, 10.2 and 11.3 are addressed in the compliance responses to those subcriteria. In general the QA organization is not directly responsible for verification of conformance to design (data

acquisition/analysis), inspection or test evaluation requirements, but it does ensure that verification by others has been properly performed and documented.

"1.12 Persons and organizations performing QA functions have direct access to management levels which will assure the ability to:

a. Identify quality problems.

b. Initiate, recommend, or provide solutions through designated channels.

c. Verify implementation of solutions.

d. Stop unsatisfactory work.

The persons and organizations with the above authority are identified and a description of how those actions are carried out is provided."

Compliance Response

Subcriterion 1.12 and Subcriteria 1.12a, b, c and d are addressed on page 01-8 of the program, second paragraph, items 1, 3, and 4, which provide the QA Manager with direct access to management and with the authority to identify quality problems, initiate their solutions, verify implementation and to recommend to appropriate management that unsatisfactory work be stopped.

As shown in page 01-1, second and third paragraphs, and on Figures 01-1 through 01-5 of the program, the Executive Director, Administrator of Technical Programs, Project Managers, and Principal Investigators, to whom the QA Manager has access, have the authority to ensure any assistance the QA Manager needs to perform his/her functions.

Details of how these actions are carried out are provided by QA procedures. For example, procedure QAP-15.1, "Nonconformances," Subsection 4.1, lists three ways by which the QA Manager can identify quality problems: from audits conducted by the QA Manager, from surveillance reports conducted by or for NWPO, or from direct communication from inspectors or other NWPO, contractor, subcontractor or vendor/supplier personnel observing apparent nonconformances. To initiate solutions of nonconformances, the QA Manager issues a nonconformance report NCR (Subsection 4.2) and ensures that corrective action is taken and verified in accordance with procedure QAP-16.1, "Corrective Action." See procedure QAP-16.1, Figure 8.0-1 for a summary. See procedure QAP-18.1, "Audits" for identification and resolution of audit findings and observations.

The subject of stop-work orders is addressed in procedure QAP-16.1 (see Figure 8.0-1). Nonconformances identified as significant conditions adverse to quality (SCAQ) may require stop-work orders. In these cases, the QA Manager confers with the Executive Director who may issue a stop-work order, as appropriate. (Procedure QAP-16.1, Subsection 4.10.1).

"1.13 Provisions are established for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and other department personnel."

Compliance Response

This matter is addressed on page 01-9 of the program, second paragraph, which states that, "Differences of opinion between the QA Manager and other NWPO personnel or con-tractor/subcontractor or vendors/supplier staff are resolved by the Executive Director."

"1.14 Policies regarding the implementation of the QA program are documented and made mandatory."

Compliance Response

This subcriterion is addressed in the Statement of Quality Assurance Policy signed by NWPO's Executive Director which documents NWPO's implementation policies and which states on page 1, second paragraph that, "It is NWPO's policy to ensure that NWPO and its contractors and subcontractors perform their activities in conformance with applicable written quality assurance and technical procedures that conform to the NWPO Quality Assurance Program. To help accomplish this purpose, NWPO uses procurement contract documents to require conformance of vendor-supplied materials and equipment, and of contractor/subcontractor services to NWPO's Quality Assurance Program and procedures." Further, on page 01-7 of the program, third paragraph, there is a statement, "...NWPO requires all NWPO, contractor/subcontractor, and vendor/supplier personnel to follow the QA program and QA and technical procedures as documented by the NWPO QA Manual."

"1.15 The persons responsible for directing and managing the overall QA program are identified and have appropriate organizational position, responsibilities, and authority to exercise proper

control over the QA program. These individuals are free from non-QA duties and can thus give full attention to assuring that the QA program is being effectively implemented."

Compliance Response

Page 01-7, second paragraph of the QA program, assigns responsibility for the QA program and procedures to the QA Manager and page 01-8 of the program, third paragraph and 01-9, first paragraph, give the QA Manager the authority to exercise proper control of the QA program. As indicated on page 01-7, second paragraph, and Figure 01-1, the QA Manager reports directly to the highest level of authority, the Executive Director. Page 01-7, second paragraph requires the QA Manager to devote, "... his/her time exclusively to quality assurance functions." See the responses to Subcriteria 1.10 and 1.10a.

Additional Statement

Besides addressing criteria of the NRC Review Plan, Section 01 of the QA program discusses qualifications of persons performing tasks governed by the program. "Documentation of qualifications of individuals performing activities covered by the QA program is addressed by procedure QAP-1.1, governing position titles and descriptions, employee experience records, and employee qualifications of NWPO's contractors' and subcontractors' participating staffs and by procedure QAP-3.3, governing qualifications of peer reviewers (page 01-7 of the program, third paragraph). As specified in procedure QAP-1.1, "Position Titles,

Position Descriptions, Employee Experience Records, and Qualification Statements," the Administrator of Technical Programs, Project Managers, and the Executive Director assume responsibility for qualifications and suitability of persons who direct, manage, or implement activities controlled by the NWPO QA Program (Section 1.0 and Subsections 4.10 through 4.11.1).

Section 02 - Quality Assurance Program

"2. Activities related to Quality Assurance Program are acceptable to the NRC staff if:

2.1 The QA program includes all items and activities important to safety and waste isolation as defined in 10 CFR Part 60.2. The items and activities covered by the QA program are identified and the rationale provided for determining how items or activities are important to safety or waste isolation, as defined in 10 CFR Part 60.2. These terms are defined as numerical performance objectives and standards. The rationale should include systems analyses that are used to determine what specific items and activities are covered."

Compliance Response

This subcriterion is not applicable to NWPO's QA Program. NWPO has written its program, "... to control activities essential to attainment of NWPO's objectives as specified in the Statement of Quality Assurance Policy ... and in procurement contract documents," (page 02-1 of the program, first paragraph) and these objectives do not necessarily coincide with the DOE's objectives or activities whose importance is defined in 10CFR Part 60.2. See page 00-1, second paragraph; additional sentences of page 02-1, first paragraph; page 03-1, first paragraph, and Figures 01-2 through 01-5, of the QA program for indication of technical activities covered by the QA program, and for the rationale behind the program.

Objectives and rationale stated in the program and procurement contract documents are estalished by NWPO in consultation with the Technical Advisory Group and/or with others. See page 01-7, second paragraph which states that, "...the Technical Advisory Group is a high-level council of independent consultants retained by NWPO to provide non-mandatory guidance as requested." See, also page 04-1, third paragraph, item 1 which states that, "The Executive Director and Administrator of Technical Programs (in consultation with others) set procurement goals...," and procedure QAP-4.1, "Procurement Contract Control and Contractor/Subcontractor Qualification," Subsection 4.2, which states that, "The Executive Director and/or Administrator of Technical Programs shall consult with the Technical Advisory Group and/or with other qualified individuals concerning activities... necessary to achieve NWPO's goals and objectives."

NWPO does not consider numerical performance objectives nor systems analysis to be relevant to its choice of goals and objectives.

"2.2 The QA program includes a commitment that all development, control, and/or use of computer programs will be conducted in accordance with the QA program. Guidance for the content of documentation of computer codes is provided by NUREG-0856, 'Final Technical Position on Documentation of Computer Codes for High-Level Waste Management'."

Compliance Response

In general, "...all NWPO, contractor and subcontractor activities... must be... controlled by QA and/or technical procedures..." (page 02-2 of the program,

third paragraph) and computer programs are no exception. In particular, see page 02-1, first paragraph which states that, "The program is in compliance with requirements of... NUREG-0856, as they apply to NWPO objectives, needs, and activities." See, also, page 03-2, first paragraph, which states that "All development control, and/or use of computer programs... conforms to the intent of NUREG-0856..." Also relevant is page 06-2, second paragraph, which states that, "Computer activities adhere to the applicable requirements of NUREG-0856," and page 06-1, item 10, in which computer-activity documents are listed with documents subject to QA control. See also procedure QAP-3.1, "Calculations," Section 1.0, Subsections 4.3.5 through 4.3.8, and Subsection 4.5.2 for an example of procedural control of computer activities. Much of the text of procedure QAP-3.1 is derived from NUREG-0856.

"2.3 Provisions are established to assure that technical and quality assurance procedures required to implement the QA program are consistent with QA program requirements and are properly documented, controlled, and mandated through a policy statement or equivalent document signed by a responsible official."

Compliance Response

Requirements of this acceptance subcriterion are addressed by the second paragraph of page 02-1 and by the first paragraph of page 02-2 of the program as follows: "The NWPO QA Program is implemented by quality assurance procedures and by NWPO and contractor/subcontractor technical procedures listed in

the Tables of Contents of each manual volume. All procedures and revisions thereto are prepared, reviewed and approved, distributed and controlled in accordance with QA Procedures QAP-2.1 and, as applicable, QAP-2.2. QA procedures are prepared by the QA Manager... The QA Manager approves all QA procedures and reviews and approves all technical procedures for conformance to QA requirements and to the Statement of Quality Assurance Policy." The above requirements are reinforced by the Statement of Quality Assurance Policy, signed by the Executive Director, which requires on page 1, second paragraph, that NWPO (i.e., the QA Manager) perform its activities (i.e., preparation, review, approval of procedures) in accordance with implementing procedures (i.e., QAP-2.1 and QAP-2.2) that conform to the NWPO QA Program (i.e., Section 02 quoted above). The same statement also requires adherence of contractors/subcontractors to the procedures and program (i.e., they must submit technical procedures to the QA Manager for review and approval).

See procedure QAP-2.1, "Preparation, Control, and Distribution of the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Manual," and QAP-2.2, "Preparation and Control of Technical Procedures" for further details of procedure preparation, control, format, and content. See procedure QAP-2.1, Subsection 4.5, and QAP-2.2, Subsections 4.8 and 4.15, for documentation of QA approval by signature of the QA Manager and for adherence of procedures to requirements of the QA program. See Procedure QAP-2.1 for details of procedure control.

"2.4 The QA organization reviews and documents concurrence with the quality-related* procedures relative to QA requirements."

(*The term 'quality-related' refers to the quality of items 'important to safety' or 'important to waste isolation.')"

Compliance Response

As shown in the response to Subcriterion 2.3, above, the QA Manager reviews and documents the concurrence of all QA and technical procedures with QA requirements. With reference to the term "quality-related," NWPO uses the term in connection with services, materials, apparatus, or instruments essential to NWPO's goals and objectives which are not necessarily those of the DOE.

"2.5 The QA organization and the necessary technical organizations participate early in the QA program definition stage to determine and identify the extent QA controls are to be applied to specific items and activities. This effort involves applying a defined graded approach in accordance with importance to safety or waste isolation as defined in 10 CFR Part 60.2 and affects such disciplines as design, data analysis (such as performance assessment), procurement, document control, inspections, tests, special processes, records, audits, and others described in 10CFR Part 50, Appendix B."

Compliance Response

As defined by this subcriterion, graded approach to QA control is inappropriate to NWPO-sponsored activities. See responses to Subcriteria 1.8 and 2.1, above, for a discussion of how NWPO establishes its objectives and determines the extent of necessary QA controls.

"2.6 Existing or proposed QA procedures and detailed technical procedures are identified and documented reflecting that each criterion of 10CFR Part 50, Appendix B, appropriate to specific items and activities, will be met.

Compliance Response

This subcriterion is addressed by lists of QA procedures and technical procedures shown in the QA manual Tables of Contents, referred to in the program text, by text reference to specific procedures, and by the procedures themselves included with the manual. "The current revision status of all procedures is indicated in the NWPO QA Manual Tables of Contents included in each volume of the manual. QA... and technical procedures... are numbered to correspond to the section of the program they implement. For example,... QAP-6.1 addresses Section 06..." (page 02-2 of the program, first and second paragraphs).

"2.7 A description is provided of how management (above or outside the QA organization) regularly assesses the scope, status, adequacy, and compliance of the QA program to 10CFR Part 50, Appendix B. These measures should include:

a. Frequent contact with program status through reports, meetings, and/or audits.

b. Performance of an annual assessment which is preplanned and documented with corrective action identified and tracked."

Compliance Response

This acceptance criterion is addressed on page 02-4 of the program, first paragraph, which reads, "Independent assessment of the scope, status, adequacy, and compliance of

the program with 10CFR50, Appendix B, and other controlling documents, is accomplished by the Executive Director who maintains close and continuous contact with the QA program through frequent informal meetings and reports from the QA Manager and other program participants. In accordance with procedure QAP-2.4, the Executive Director also receives an annual effectivity report from the QA Manager summarizing the effectiveness of the QA procedures and program in attaining NWPO's quality assurance objectives. The Executive Director also performs an annual preplanned and documented assessment of program effectivity and compliance, either directly or through an outside consultant and ensures any necessary corrective action."

Procedure QAP-2.4, "Management Assessment of the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Program," gives further details. With reference to documentation of the annual management assessment and verification and tracking of corrective action, "The Executive Director may... initiate a management audit of the QA Manager's activities to be performed by the Executive Director or an outside consultant..." (Subsection 4.1.1). "The QA Manager shall be responsible for implementation of any corrective action or recommendations of the management report, for any recommendations taken from the effectivity report, as well as for any corrective action resulting from any management audit... The Executive Director shall be responsible for documented tracking and verification of implementation" (Subsection 4.15).

"2.8 Indoctrination, training, and qualification programs are established such that:

a. Personnel responsible for performing quality-related activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.

b. Personnel verifying activities affecting quality are qualified in the principles, techniques, and requirements of the activity being performed.

c. For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance.

d. Appropriate management monitors the performance of individuals involved in activities affecting quality and determines the need for retraining and/or replacement. A system of annual appraisal and evaluation can satisfy this criterion.

e. Qualified personnel are certified in accordance with applicable codes and standards."

Compliance Response

Requirements of this acceptance criterion are satisfied on pages 02-4 and 02-5 of the program, first and second paragraphs, respectively, and by procedure QAP-2.3, "Indoctrination and Training in the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Manual."

Subcriterion 2.8a and part of Subcriterion 2.8b are addressed by items 1 and 2 (page 02-4) which state,

"1. All NWPO and contractor/subcontractor staff personnel performing significant activities governed by the QA program are trained in the QA program and appropriate QA procedures by the QA Manager prior to performing their tasks.

2. Prior to performing their activities, all contractor/subcontractor and NWPO personnel receive training in appropriate technical procedures by the Principal Investigator, Project Manager (or designee), or by the Administrator of Technical Programs (NWPO personnel only)."

Further, with respect to Subcriterion 2.8b, only technically qualified personnel can become verifiers ("It is NWPO's policy to require that reviewers/verifiers be... qualified persons..." (page 03-2 of the program, second paragraph) and "...supervisors are responsible for assigning qualified reviewers/verifiers" (page 03-2, third paragraph).) Qualifications of personnel are determined by procedure QAP-1.1, "Position Titles, Position Descriptions, Employee Experience Records and Qualification Statements." In addition, procedure QAP-2.3 requires that, "...no... individual performs significant activities... until that individual has satisfactorily completed training... in those... technical procedures applicable to his/her responsibilities" (Subsection 4.1). Thus, for example, all calculation reviewers (verifiers) must be trained in procedure QAP-3.1,

"Calculations" and persons responsible for assigning calculation reviewers (verifiers) must assign qualified persons (see procedure QAP-3.1, Subsections 4.12 and 4.14, and the glossary definition of Reviewer; Technical Reviewer).

Subcriterion 2.8c is addressed by item 3, page 02-4 of the program, "Trainees are instructed in the purpose, scope, and implementation of the program and procedures. As indicated in procedure QAP-2.3, training is adequately documented," and by procedure QAP-2.3, Subsections 4.6, 4.8, 4.12.1, 4.13, and 5.1.1 through 5.1.8. For example, Subsection 4.12.1 requires that, "...Attendance shall be documented," and Subsection 4.13 that, "Satisfactory completion of technical training shall be documented..."

Subcriterion 2.8d is satisfied by items 4 and 5 on page 02-5 and in procedure QAP-2.3, Subsection 6.5, which requires that, "The Administrator of Technical Programs, Project Managers, Principal Investigators or Designees shall monitor performance of personnel and institute retraining or other appropriate action as necessary." NWPO feels that an annual assessment requirement is too restrictive considering the scale of NWPO-sponsored activities.

The intent of Subcriterion 2.8e is addressed on page 02-5, immediately below item 5, "Personnel are qualified in accordance with applicable standards and procedures." At present, NWPO does not forsee any activity that requires certification.

Additional Statement

1. In addition to addressing criteria of the NRC Review Plan, Section 02 of the QA Program provides for organized review of current NRC, DOE, and industry codes, regulations, guidelines, and technical documents for their impact on the NWPO QA Program and implementing procedures. Changes to the program or procedures are instituted as needed. See page 02-5 of the program, third paragraph, and procedure QAP-2.5, "Review of Documents and Technical Information for Impact on the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Manual."

2. In recognition of the unpredictable nature of certain research or development activities, the program (page 02-2, fourth paragraph and page 02-3, first paragraph) permits performance of said activities without prior specification of methodologies provided certain specified conditions are met. NWPO feels that this provision is necessary to accommodate special aspects of NWPO's objectives.

Section 03 - Design Control (Analysis of Site Characterization Data)

"3. Activities related to Design Control are acceptable to the NRC staff if:

3.1 The definitions of design, design information, and design activities used in the design control program are as defined in this section. The term design refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system. It includes designs at each stage of design development (i.e., from conceptual design to final design). Design information and design activities refer to data collection and analyses activities that are used in supporting design development and verification. This includes general plans and detailed procedures for data collection and analyses and related information such as test results and analysis. Data analysis includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters. The above is consistent with the definition and usage of these terms in 10 CFR Part 60 and the Atomic Energy Act of 1954."

Compliance Response

The intent and requirements of this subcriterion are accepted in principle on page 03-1 of the QA program, first paragraphs. In NWPO's view the use of the word "design" to denote NWPO-sponsored activities would be misleading and counterproductive. Accordingly, the terms "data acquisition" and "date analyses," corresponding substantially to the terms "design information" and "design activity" have been employed

in the program and procedures. "Activities performed by NWPO and its contractors and subcontractors in connection with site characterization at Yucca Mountain consist of data acquisition and data analyses. For purposes of NWPO's QA Manual the terms 'data acquisition' and 'data analyses' correspond substantially to the terms 'design information' and 'design activity' as defined by the... NRC... Neither NWPO, nor its contractors or subcontractors design repository systems but, rather, are concerned with activities related to acquisition and analyses of data, largely of a geologic/geotechnical nature that the DOE may or should use as a basis for any design it may choose to propose or any feasibility recommendations it may choose to make..." (page 03-1 of the program, first paragraph).

Responses to other subcriteria of Criterion 3, below, apply only to "data acquisition/data analyses" ("design information"/"design analyses") activities as explained above.

"3.2 The design control program is implemented at the time of submission of the Site Characterization Plan and includes design and design activities as described in 3.1. It provides for the correct translation of applicable regulatory requirements and design bases into design, procurement, and procedural documents. Performance requirements are specified for repository system components to support: (a) identification of which items are important to waste isolation; (b) establishment of a graded QA approach; and (c) establishment of data gathering and analysis needs."

Compliance Response

Requirements of this acceptance subcriterion are not, for the most part, applicable to NWPO's objectives, program or activities. NWPO does not submit a site characterization plan nor does it set performance requirements for repository system components or employ a graded QA approach (see responses to Subcriteria 1.8, 2.1, and 2.5, above).

NWPO's QA Program and Procedures will be implemented in time for the start of NWPO-sponsored work activities. See, for example, page 02-2 of the program, third paragraph, which states that, "to ensure early interaction between the QA Manager and... contractor... organizations, all NWPO, contractor and subcontractor activities... significant to (NWPO's) objectives must be authorized and controlled by QA and/or technical procedures...", procedure QAP-2.1, Subsection 4.8.1, requiring procedure distribution prior to start of work, and page 02-4, items 1 and 2, requiring training in QA and technical procedures prior to start of work.

The QA program provides for translation of NWPO's objectives and requirements into appropriate documents. For example, procurement documents must include as applicable, "...a statement of scope, purposes, and objectives of the work including... an outline of methodologies... technical requirements including... accuracy and precision criteria..." (page 04-2, items 3b and 3c) and, as another example, technical procedures provide for, "...traceability of calibration standards to nationally recognized standards..." (page 12-1 of the program, third paragraph).

"3.3 Organizational responsibilities are described for preparing, reviewing, approving, verifying and validating design and design information documents."

Compliance Response

This subcriterion is addressed on page 03-1 of the program, second paragraph, which states that, "NWPO, through the Administrator of Technical Programs, ensures documented preparation, independent review (or other form of verification), and (as needed) approval, and validation of NWPO-generated data acquisition or analysis documents in accordance with the QA program and procedures. In a like manner, the contractors, through the Project Managers, Principal Investigators, Laboratory Directors, or designees, ensure the same for documents generated by contractors or subcontractors." See procedure QAP-3.2, "Technical Reports," Subsections 4.1 through 4.1.2 for an example of how this is implemented. See, also, page 06-2 of the program, second paragraph.

"3.4 Errors and deficiencies in approved design and design information documents are documented, and action is taken to assure that all errors and deficiencies are corrected."

Compliance Response

Errors and deficiencies in approved or verified data acquisition/analysis documents are considered to be nonconformances (page 15-2 of the program, item 5) and discovered, documented and corrected in accordance with procedures QAP-15.1, "Nonconformances," QAP-16.1, "Corrective Action" and, as appropriate, QAP-18.1, "Audits."

For example, see procedure QAP-15.1, Subsection 4.10, which states that, "The QA Manager shall initiate a nonconformance report immediately upon notification of a nonconformance..." and procedure QAP-16.1, Section 1.0, which states that, "...corrective action encompasses errors and deficiencies to approved output or verified input/support documents." See, also, procedure QAP-16.1, Figure 8.0-1, and Sections 15 and 16 of the QA program. Refer to compliance responses to Criteria 15 and 16, below.

"3.5 Interface controls among organizations or groups involved in design development and other design activities are described."

Compliance Response

For the most part the nature of NWPO-sponsored activities does not necessitate interface controls as stringent as would be needed for design organizations. However the program and procedures provide whatever interface controls are needed.

Requirements of this acceptance subcriterion are addressed in Section 01, "Organization," of the QA program, on page 01-1, second and third paragraphs, page 01-7, first paragraph, and on Figures 01-1 through 01-5 (pages 01-2 through 01-6). "The Administrator of Technical Programs coordinates contractor, subcontractor, and vendor/supplier activities through the contractor Project Managers... The Project Managers coordinate the activities of the Principal Investigators. The Principal Investigators perform... tasks... with the aid of... subcontractors,

and vendors/suppliers, whose activities they supervise and/or coordinate... Interface relations between Principal Investigators are coordinated by the Project Managers; relations between contractors are regulated by the Administrator of Technical Programs."

To facilitate interface relations Section 06 of the program (page 06-2, third paragraph and page 06-3, first paragraph) and procedures QAP-6.1, "Document Distribution List and File Index" and QAP-6.2, "Progress Reports and Master Document Lists" assure circulation of documents among participating organizations. Also, procedures QAP-2.1 (Figure 4.1-2, Section 3.0) and QAP-2.2 (Figure 4.17-1, Section 3.0) require listing of interfacing procedures in all QA and technical procedures.

"3.6 Procedures require that design drawings, specifications, criteria, and analyses be reviewed by the QA organization to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements."

Compliance Response

Requirements of this acceptance criterion, as they apply to data acquisition/analyses documents, are satisfied by Section 18, "Audits," of the program, and by procedure QAP-18.1, "Audits," as follows. "The QA Manager performs... audits of... procedures... (and)... documents... to seek-out and evaluate... evidence of compliance with the NWPO QA Program... (and)... procedures...," including the requirement of documented preparation, review and approval (page 18-1 of the

program, second paragraph). "...audits are performed... in accordance with procedure QAP-18.1..." (page 18-1 of the program, first paragraph). For example, calculations are audited per procedure QAP-18.1 for documentation (signatures) that they have been prepared, reviewed, and approved per procedure QAP-3.1, "Calculations."

Aside from audits, the QA Manager reviews procurement documents, which include specifications, prior to issuance, to ensure proper preparation, review, and approval (see procedure QAP-4.1, "Procurement Contract Control and Contractor/Subcontractor Qualification," Subsection 4.8).

See procedure QAP-15.1, Subsections 4.3 through 4.8, for alternate means of discovery of improperly reviewed documents.

"3.7 Procedures are established and described for verification of designs and design activities, the verifier of which is qualified and not directly responsible for the design (i.e., not the performer or his immediate supervisor). In exceptional cases, the designer's immediate supervisor can, however, perform the verification, provided:

(a) The supervisor is the only technically qualified individual.

(b) The need is individually documented and approved in advance with concurrence of the quality assurance Manager.

It is preferable to have qualified personnel not associated with the responsible design organization conduct verification activities."

Compliance Response

1. The first part of this acceptance subcriterion (verification procedures) is addressed on page 03-2 of the program, second paragraph, "Review/verification of data acquisition/analyses documents and activities, including the reviewer's/verifier's responsibilities and techniques, the scope of review/verification, and the extent of documentation, is governed by procedures." Examples of such procedures are QAP-3.1, "Calculations," QAP-3.2, "Technical Reports," and QAP-4.1, "Procurement Contract Control and Contractor/Sub-contractor Qualification."

2. NWPO uses the term "review/verification" and similar terminology in the QA program and procedures in connection with data acquisition/analysis documents to distinguish between final output documents, such as technical reports, where technical review and approval is mandatory, and input/support documents, such as field notes, where full scale review, as part of a prepare-review-approve cycle, may not be feasible or necessary. (See page 03-1 of the program, second paragraph, 03-2, first paragraph, and page 06-2, second paragraph.) The glossary definition of verification, largely based on NQA-1-1986, Supplement S-1, recognizes other methods of determining compliance with requirements (e.g., checking) besides reviewing.

3. With respect to verifier's independence the second paragraph of page 03-2 indicates that, "It is NWPO's policy to require their reviewers/verifiers be independent, qualified persons not directly involved in the work they review." However, with respect to reviews by supervisors, the paragraph complies with requirements of NQA-1-1986, Supplement 3S-1, Section 4, page 16, rather than with those of the acceptance subcriterion. In effect the supervisor can be a reviewer/verifier, even if he/she is not the only competent, available individual, provided that absence of bias can be demonstrated. ("The supervisor did not specify a singular data acquisition/analyses approach, or rule out certain data acquisition/analyses considerations, and did not establish the inputs used in the data acquisition/analysis" (page 03-2 of the program, second paragraph, item 2.)) In many instances the supervisor may be the only readily available and competent verifier/reviewer of NWPO-sponsored activities.

"3.8 For design or design activities which involve use of untried or state-of-the-art testing and analysis procedures and methods or where detailed technical criteria and requirements do not exist or are being developed, a peer review should be conducted. The procedures defining the selection process for a peer group, and the process by which the peer group conducts its review should be described. A peer review is a critical review performed by personnel who are independent of, but have expertise equivalent to, those who performed the work. Outside consultants are retained for needed expertise, where required."

Compliance Response

Requirements of this acceptance subcriterion are satisfied in the QA program and in procedure QAP-3.3, "Peer Reviews." "Procedures, activities, data, assumptions, extrapolations, and results that involve untried or beyond the state-of-the-art investigation, data acquisition and analyses procedures and methods of a type for which technical criteria are nonexistent or under development are controlled by procedure QAP-3.3, "Peer Reviews." Peer reviewers are specially qualified persons selected by the Executive Director and QA Manager with the advice of the Technical Advisory Group and/or others such as the Project Manager and Principal Investigators as needed." (page 03-2 of the program, third paragraph; page 03-3, first paragraph. Many details of procurement of peer reviewers' services are spelled out in procedure QAP-4.1, "Procurement Contract Control, etc." which is cross-referenced in procedure QAP-3.3, Subsection 4.4.1).

"Activities of peer reviewers, review of work in progress, as well as selection of peer reviewers are conducted in accordance with procedure QAP-3.3, which conforms, as applicable, to the intent of the NRC Generic Technical Position on peer review (NUREG-1297) referenced in Section 00, herein." (page 03-3, first paragraph). In keeping with current NRC terminology as indicated in NUREG-129, the program and procedures use the term "beyond the state-of-the-art" instead of "state-of-the-art" to describe the scope of peer review activities.

In addition to duties indicated by the Generic Technical Position, peer reviewers may review technical procedures (procedure QAP-2.2, Subsection 4.19) or may participate in qualification investigations of potential contractors (procedure QAP-4.1, Subsection 4.12.1). Peer group selection and conduct of the peer review are included in procedure QAP-3.3, Subsections 4.1 through 4.6.3.

"3.9 The responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation are identified in the procedures."

Compliance Response

See page 03-2 of the QA program, second paragraph, referred to in the response to Subcriterion 3.7, parts 1 and 2. In particular, see procedure QAP-4.1, which states that, "The Reviewer(s) shall review the procurement document for technical adequacy, clarity of expression, adherence to requirements of Figure 4.3.1... and conformity with NWPO's objectives and return his/her comments in writing..." (Subsection 4.4); also, that review documentation is maintained in the NWPO Records Center (Subsections 5.2 and 5.2.3). Likewise, "The Reviewer of the technical procedure shall review the draft... (technical procedure)... for technical conformance with requirements... (of procedure QAP-2.2)..." (procedure QAP-2.2, Subsection 4.5). The Reviewer must comment in writing (Subsections 4.5.1 and 4.5.2).

"3.10 Design changes, including field changes, are subject to the same design controls that were applicable to the original design. Such a configuration control system should be in place at the

earliest practicable time. These changes should be analyzed to assure that change is required. Associated changes to procedures and training should be considered, and changes should be communicated to all affected groups or individuals."

Compliance Response

The NWPO QA Program and procedures are in compliance with requirements of this subcriterion except that field changes are not applicable to NWPO-sponsored activities. "Changes in data acquisition/analyses activities are accomplished by revisions to their controlling QA or technical procedures as indicated by the procedures themselves and retraining is instituted as necessary in accordance with Section 02, herein, and procedure QAP-2.3." (page 03-3 of the program, second paragraph).

With reference to need for change, procedures controlling generation of data acquisition/analyses documents (e.g., procedures QAP-3.1, QAP-3.2 and QAP-4.1) assign responsibility for authorization of preparation of original documents and specify that revisions must be prepared, reviewed (verified), and approved in the same manner as the originals. Approval of the revision constitutes endorsement that change is needed. Thus for example, in procedure QAP-3.2, "Technical Reports," "The Administrator of Technical Programs, Project Managers, Principal Investigators, Laboratory Directors, or Designees shall identify the technical activities within their respective control requiring technical reports..." (Subsection 4.1) and

"Revisions to technical reports shall be prepared, reviewed, approved, and distributed in accordance with the requirements in this procedure for the original technical report..." (Subsection 6.1). Similar requirements apply to changes in QA or technical procedures. For example, "...(contractor generated) technical procedures... must be authorized by the Principal Investigator or Project Manager..." (procedure QAP-2.2, Subsection 4.10).

Concerning communication of changes, all controlling procedures require distribution of output documents in accordance with procedure QAP-6.1, "Document Distribution List and File Index" (see, for example, procedure QAP-3.2, Subsection 5.1) and, as shown above, this requirement is applicable to revisions.

Document users are required to consult master document lists (MDLs) to verify use of current revisions of documents (procedure QAP-6.2, Subsection 6.3). Distribution of new or revised QA or technical procedures is controlled by procedure QAP-2.1. See page 06-2 of the program, third paragraph and page 06-3, first paragraph for a summary of distribution of documents and revisions (changes) thereto.

Section 04 - Procurement Document Control

"4. Activities related to Procurement Document Control are acceptable to the NRC staff if:

4.1 Procedures are established for the review of procurement documents by QA personnel to determine that applicable regulatory requirements, design bases, and other requirements are referenced or stated in procurement documents; there are adequate acceptance and rejection criteria, where appropriate; and procurement documents have been prepared, reviewed, and approved in accordance with QA program requirements. Procurement documents should require contractors, subcontractors and consultants to provide an acceptable quality assurance program."

Compliance Response

The NWPO QA Program and procedures are in compliance with this acceptance subcriterion with some exceptions; (1) "off-the-shelf" items such as measuring tapes or standard laboratory supplies are excluded (page 04-1 of the program, first paragraph), and (2) contractors/subcontractors do not provide quality assurance programs because their activities are governed by NWPO's QA Program. Also, as shown below, the QA Manager reviews procurement documents for QA requirements but not for technical requirements as implied by items such as "design bases" and "acceptance and rejecting criteria" used in the subcriterion. These types of items are reviewed by others as indicated in procedure QAP-4.1. See page 02-1 of the program, first paragraph, page 00-1, third paragraph and page 18-1, first paragraph. See, also, response to Subcriteria 1.2 and 1.4, above.

With reference to other items, "Requirements of QA Program Sections 04 and 07... are implemented by procedure QAP-4.1 and by ancillary technical procedures" (page 04-1 of the program, third paragraph). As shown in Section 04 of the program, the principal vehicle for establishment of QA and technical requirements is the procurement document, which is a part of the procurement contract.

With specific reference to review of procurement documents by QA personnel, "The QA Manager performs a documented review of all procurement documents for compliance with QA requirements" (page 04-2 of the program, item 2); "The QA Manager shall review the procurement document to ensure that it was properly prepared, reviewed, and approved..." (procedure QAP-4.1, Subsection 4.8). "All final contracts are reviewed by the QA Manager ..." (page 04-4 of the program, item 5).

As indicated in the QA program (pages 04-2 and 04-3, items 3a through 3j) and in procedure QAP-4.1, Figure 4.3-1, the procurement documents reviewed by the QA Manager and others must include applicable regulatory requirements and acceptance/rejection criteria (Figure 4.3-1, item 3) as well as the scope, purpose, objectives and methodologies of the activity to be performed. The contractors/subcontractors must comply with the NWPO QA Program and procedures as well as prepare new technical procedures as needed (page 04-3 of the program, item 3i; procedure QAP-4.1, Figure 4.3-1, item 9).

"4.2 Organizational responsibilities are described for: (1) procurement planning; (2) the preparation, review, approval, and control of procurement documents; (3) supplier selection; (4) bid evaluations; and (5) review and concurrence of supplier QA programs prior to initiation of activities affected by the program. The involvement of the QA organization is described."

Compliance Response

With reference to item (1) of this acceptance criterion, above, "...NWPO is responsible for overall procurement planning..." (page 04-1 of the program, second paragraph). "The Executive Director and Administrator of Technical Programs... set procurement goals..." (page 04-1, item 1). See, also, procedure QAP-4.1, Subsection 4.2.

With respect to item (2) of the subcriterion, "...NWPO is responsible... for procurement of contractor services... for procurement of materials and equipment for its own use... (and)... for review and approval of contractors' procurement activities... The contractors are responsible for procurement of subcontractor services... (and)... for procurement of materials and equipment from vendors/suppliers for contractor/subcontractor use..." (page 04-1 of the program, second paragraph). For details, see procedure QAP-4.1, Subsections 4.4.1, 4.14 through 4.16.1, and 4.16.4). See, also, page 04-1 of the program, item 1, page 04-2, item 2, and procedure QAP-3.3, Subsection 4.4.1. See compliance response to Subcriterion 7.2, below, for NWPO's definition of vendor and supplier.

With respect to item (3) of the subcriterion, NWPO is responsible for selection of vendors/suppliers furnishing materials and equipment for NWPO's own use and the contractor (subject to NWPO's final approval) is responsible for selection of vendors/suppliers furnishing materials or equipment for contractor's or subcontractor's use. See response to item (2) above.

Concerning item (4) of the acceptance subcriterion (bids), "NWPO and contractors... evaluate proposals (bids)..." (page 04-1 of the program, second paragraph). NWPO evaluates bids (proposals) for services of contractors and for materials and equipment to be furnished for NWPO's own use (procedure QAP-4.1, Subsections 4.11 through 4.12.1). Subject to final NWPO approval the contractors evaluate proposals for subcontractor services and for materials and equipment to be furnished by vendors/suppliers for contractor or subcontractor use (procedure QAP-4.1, Subsections 4.16 through 4.16.3) and pages 04-3 and 04-4 of the program, Item 4, "The Executive Director/ Administrator of Technical Programs/QA Manager (or Project Manager/Principal Investigator/QA Manager) investigate and evaluate the qualifications of potential contractors, subcontractors, and vendors/suppliers of interest." (pages 04-3 and 04-4, item 4).

Item (5) of the subcriterion does not apply to NWPO's program or to NWPO-sponsored activities. See response to Subcriterion 4.1, first paragraph, and to Subcriterion 1.2.

See, also, compliance response to Subcriterion 7.2.

Section 05 - Instructions, Procedures, and Drawings

"5. Activities related to Instructions, Procedures, and Drawings are acceptable to the NRC staff if:

5.1 Organizational responsibilities are described for assuring that quality-related activities are: (1) specified in instructions, procedures, and drawings; and (2) accomplished through implementation of these documents. These documents should be verified and approved as described in Section 3.

5.2 Procedures are established to assure that instructions, procedures, and drawings include acceptance criteria for determining that quality-related activities have been satisfactorily accomplished."

Compliance Response

The NWPO QA Program and procedures are in compliance with the intent of Subcriteria 5.1 and 5.2.

With respect to Subcriterion 5.1, "Significant NWPO, contractor and subcontractor activities are governed by QA and technical implementing procedures issued in accordance with procedures QAP-2.1 and QAP-2.2. When instructions and drawings are used to specify activities they are included as parts of the procedures (page 05-1 of the program, first paragraph). "Technical activities performed by NWPO, contractors, subcontractors, and vendors/suppliers shall be controlled by technical procedures. Technical procedures governing NWPO technical activities shall be prepared by NWPO, and technical procedures governing

contractor, subcontractor, or vendor/supplier activities shall be prepared by the appropriate contractor or subcontractor" (procedure QAP-2.2, Subsection 4.1). This is further illustrated as follows, "Contractors' responsibilities are to perform technical tasks..." (page 01-7 of the program, fourth paragraph). "...contractors' and subcontractors' specific responsibilities are indicated in QA and technical procedures..." (page 01-8, second paragraph). QA and technical procedures are reviewed and approved as indicated in procedures QAP-2.1 and QAP-2.2. See, also, page 02-1 of the program, second paragraph and page 02-2, first paragraph.

With respect to implementation of QA and technical procedures, "The QA Manager... audits... activities, procedures, documents, records and facilities... (for)... compliance with the NWPO QA Program (page 18-1 of the program, second paragraph).

With reference to Subcriterion 5.2, "If required by the nature of the activities governed, implementing procedures include or reference quantitative or qualitative acceptance criteria for determining that the activities have been satisfactorily accomplished" (page 05-1, first paragraph). See procedure QAP-2.2, page 9, lines 22 and 23.

Section 06 - Document Control

"6. Activities related to Document Control are acceptable to the NRC staff if:

6.1 The scope of the document control program is described, and the types of controlled documents are identfied."

Compliance Response

As stated on page 06-1 of the program, first paragraph, "...the program addresses control of documents generated by NWPO and its contractors/subcontractors and vendors/suppliers. Document control encompasses all documents necessary to demonstrate that NWPO and contractor/subcontractor activities are conducted by qualified personnel to acceptable technical and quality assurance levels of performance... Control of geotechnical samples such as rock cores or water is addressed in Section 13 of the program."

Many of the types of documents included in the document control program are listed on pages 06-1 and 06-2 of the program. Computer tapes and computer code control procedures are among the document types listed, therein. For purposes of the QA program geotechnical samples, such as rock or water, are not considered documents but records of their custody, handling, and storage are so considered.

"6.2 Procedures for the review, approval, issuance, and revision of documents are established. These procedures assure technical adequacy and inclusion of appropriate quality requirements. The QA organization reviews and concurs with these documents with respect to quality-related aspects."

Compliance Response

This subcriterion is addressed on page 06-2 of the program, second paragraph, which states that, "Preparation, verification, review, issuance, and revision of data acquisition/analysis and other types of documents are controlled by QA and technical procedures. These procedures ensure technical adequacy and inclusion of appropriate quality assurance requirements and are reviewed and approved by the QA Manager. For data acquisition/analyses and other output documents such as calculations, technical reports, procurement documentation or QA or technical procedures, the procedures assign preparation, review, and approval responsibilities and mandate review and approval prior to issuance of documents. For input/support documents, such as laboratory or field data books not requiring formal approval, the procedures require review or other form of verification of data authenticity and completeness, as appropriate..." With further reference to document review, approval, and revision, "NWPO... ensures documented... review (or other forms of verification) and (as needed) approval... of NWPO-generated data acquisition or analysis documents in accordance with the QA program and procedures... (and)... contractors... ensure the same for documents generated by contractors or subcontractors" (page 03-1 of the program, second paragraph and 03-2, first paragraph) and "Changes in data acquisition/analyses activities are accomplished by revisions to their controlling... procedures" (page 03-3, second paragraph). See

procedures QAP-3.1, "Calculations" and QAP-3.2, "Technical Reports" for examples of procedures that control review, approval, etc., of data acquisition/ data analyses documents.

Concerning QA organization reviews, the term "documents," as used in the last part of the Subcriterion, is not entirely clear to us. The QA Manager reviews and concurs with QA and technical procedures relative to QA aspects (page 02-2 of the program, first paragraph). He/she audits but does not review and concur with technical content of documents such as calculations or technical reports. As indicated on page 18-1, second paragraph, the QA Manager audits documents generated by the procedures. Also, the "...Technical Auditors may use technical verification of work... to confirm effectiveness of review/verification..." (page 18-2 of the program, first paragraph).

Further, concerning technical adequacy and quality requirements, "The NWPO QA Program is implemented by... procedures... All procedures and revisions thereto are... controlled in accordance with... procedures QAP-2.1 and, as applicable, QAP-2.2 (page 02-1 of the program, second paragraph). Procedure QAP-2.2 controls content of technical procedures by requiring that, "...technical procedures should address applicable items listed in Figure 4.18-1, 'Content of Technical Procedures...' " (Subsection 4.18). Figure 4.18-1 lists items related to technical adequacy, such as calibration and QA items, and review/verification (page

9 of procedure QAP-2.2). In addition, technical procedures must be reviewed for technical adequacy (procedure QAP-2.2, Subsections 4.5 and 4.13).

See compliance response to Subcriteria 5.1 and 5.2, above.

"6.3 Procedures are established to assure that correct and applicable documents are available at the location where the activity will be performed prior to commencing the work.

6.4 Procedures are established and described to assure that obsolete or superseded documents are removed and replaced by applicable revisions at work areas in a timely manner.

6.5 A master list or equivalent document control system is established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents."

Compliance Response

Requirements of these acceptance subcriteria are addressed on page 06-2 of the QA program, third paragraph, and page 06-3, first paragraph, as follows, "Availability of correct, current, and applicable documents at the proper locations prior to start of work is ensured by (1) procedures QAP-6.1 and QAP-6.2 controlling document (and revised document) distribution, file indexing, progress reports and master document lists; (2) by procedures such as QAP-2.1 and QAP-2.2 controlling distribution of QA and technical procedures; and (3) by procedures, such as

procedure QAP-3.2 requiring use of current and verified input data as feasible. Procedure QAP-6.1 and other procedures such as QAP-2.1, require recipients of revised documents to promptly destroy the superseded documents or to promptly mark them 'Void' or 'Superseded.' In accordance with procedure QAP-6.2, document holders are notified of obsolete or withdrawn documents and required to destroy or suitably mark the affected documents."

Requirements of these subcriteria are further satisfied on page 06-3, second paragraph, which states that, "NWPO exercises control of NWPO, contractor, subcontractor, and vendor/supplier documents. The Administrator of Technical Programs maintains master lists of current documents compiled from progress reports..."

With reference to Subcriterion 6.3, the procedures that control the generation of data acquisition/analysis output documents require distribution of documents and document revisions to document users, per the document distribution list (DDL) of procedure QAP-6.1. See page 06-3 of the program, third paragraph, which states that, "All QA and technical implementing procedures provide for control of all documents generated by the procedure." See, also, for example, procedure QAP-3.2, Subsections 5.1 and 5.3.

"For purposes of Section 5.0 of the quality assurance and technical procedures, governing disposition of documents resulting from procedure activities,

input/support documents are processed as output documents" (Glossary entry for "Output Document").

Assurance of timely distribution of implementing procedures is provided by QAP-2.1, Subsection 4.8.1, "QA manuals... (including procedures)... shall be distributed prior to start of activities governed by the manual, as appropriate." Distribution of current procedure revisions is assured by a transmittal and receipt system (Figure 4.10-1) and by changes to the Tables of Contents of the manual (Subsection 4.7).

The intent of Subcriterion 6.3 is further met by procedure QAP-6.2, "Progress Reports and Master Document Lists," Subsections 5.1.2 and 6.3, which require that, "Distribution of MDLs shall ensure that... persons have ready access to current lists..." and that "Users of output documents shall consult MDLs... (Master Document Lists)... to verify use of current revisions of (output) documents prior to start of work affected by the documents." MDLs must also be kept current (see, for example, procedure QAP-3.2, Subsection 4.12 and response to Subcriterion 6.4, below). In addition, procedures such as QAP-3.2 require that any output documents used as input be approved (Subsection 4.2.3). By definition, input/support documents must be verified prior to issuance for use (see Glossary definition of Input/Support Document) and implementing procedures require said verification.

Requirements of Subcriterion 6.4 are answered in procedure QAP-6.2, Subsections 6.3 and 6.4, which read, "Revised MDLs shall be issued as soon as feasible... Users of output documents shall consult MDLs to verify use of current revisions of documents... Document Users shall promptly destroy superseded and obsolete or withdrawn documents listed on MDLs or mark them 'Void' or 'Superseded' or 'Withdrawn.' " Similar instructions are included with other QA and technical procedures that generate documents (e.g., procedure QAP-3.2, Subsection 6.5). Procedure QAP-6.1, Subsection 4.1, also instructs document recipients to destroy or suitably identify superseded documents. This applies to input/support documents not covered by MDLs. Similar instructions applying to input/support documents are included as part of technical procedures and similar instructions apply to superseded QA or technical procedures (procedure QAP-2.1, Subsection 4.11).

Requirements of Subcriterion 6.5 are satisfied by procedure QAP-6.2, and by procedure QAP-2.1, "Preparation, Distribution, and Control of the Agency for Nuclear Projects/Nuclear Waste Project Office Quality Assurance Manual." Procedure QAP-6.2 establishes a master document list for output documents such as technical reports and procurement contracts (Section 1.0). The QA Manual Tables of Contents serve as a listing of current QA and technical procedures (procedure QAP-2.1, Subsection 4.7; QA program, page 02-1, second paragraph).

"6.6 When documents which require verification are released prior to verification, they are so identified and controlled."

Compliance Response

Requirements of this subcriterion are included in page 06-2 of the program, second paragraph as follows. "Documents released for any reason prior to review or other form of verification (as applicable) are suitably identified," and in implementing procedures. With procedures or other parts of the QA manual, unapproved copies are considered uncontrolled and so marked (procedure QAP-2.1, Subsection 4.13). For other documents the requirements are included in the controlling procedure. For example, see procedure QAP-3.2, "Technical Reports," Subsection 4.11, "Unapproved reports released for any reason shall be marked 'Unapproved' by the Preparer."

All procedures must honor this program commitment (procedure QAP-2.1, Subsection 4.1, and QAP-2.2, Subsection 4.4).

Section 07 - Control of Purchased Materials, Equipment, and Services

"7. Activities related to Control of Purchased Materials, Equipment, and Services are acceptable to the NRC staff if:

7.1 Organizational responsibilities are described for the control of purchased material, equipment, and services."

Compliance Response

Section 07 of NWPO's QA Program does not apply to "off-the-shelf" items such as measuring tapes or standard laboratory supplies (page 07-1 of the program, first paragraph). See response to Subcriterion 1.13 concerning interpretation of what is or is not an "off-the-shelf" or standard laboratory item. Otherwise, requirements of this subcriterion are addressed on page 07-1 of the QA program, first paragraph, as follows: "NWPO exercises control of services purchased from contractors, control of equipment and materials purchased by NWPO for its own use, and final control of contractor and subcontractor purchases on NWPO's behalf. The contractors control services purchased from subcontractors and materials and equipment purchased from vendors/suppliers for contractors'/subcontractors' use. See, also, procedure QAP-4.1, "Procurement Contract Control and Contractor/Subcontractor Qualification," Subsection 4.1.

"7.2 Procedures governing procurement of items or services, including appropriate QA organization participation, provide for: (a) evaluation and selection of suppliers; (b) verification of supplier's activities; and (c) receiving inspections."

Compliance Response

For purposes of this response the term "supplier" is taken to mean contractor, subcontractor, vendor, and supplier. See response to Subcriterion 1.4, first paragraph; see the NWPO QA Manual Glossary.

Requirements of part (a) of this subcriterion are satisfied by Sections 07 and 04 of the program and by procedure QAP-4.1*, "Procurement Contract Control and Contractor/Subcontractor Qualification" as follows, "In addition to technical procedures, requirements of Section 07 are implemented by the procurement contract control procedure, QAP-4.1, of Section 04... The procedure requires the Executive Director, Administrator of Technical Programs, and QA Manager to conduct evaluation and selection of contractors, and the QA Manager, Project Manager, and Principal Investigator to do the same for subcontractors, and vendors/suppliers providing services, equipment, or materials" (page 07-1, second paragraph). "Requirements of QA program... Section... 07...are implemented by procedure QAP-4.1 and by ancillary technical procedures... In outline, procedure QAP-4.1 includes the following requirements..." (page 04-1 of the program, third paragraph). "The Executive Director/Adminis-trator of Technical Programs or Project Manager/Principal Investigator, draft contracts and requests for proposals, as needed, ... and solicit

*Procedure QAP-4.1 has been selected as an implementing procedure for Section 07 of the program because control of purchased services, etc. is closely related to their procurement.

proposals (bids) from qualified contractors/ subcontractors and vendors/suppliers. The Executive Director/Administrator of Technical Programs/QA Manager (or Project Manager/Principal Investigator/QA Manager) investigate the qualifications of potential contractors, subcontractors, and vendors/suppliers of interest" (pages 04-3 and 04-4 of the program, item 4). "NWPO's Executive Director or the contractor's Project Manager (or other Responsible Person) executes the final contract. All final contracts are reviewed by the QA Manager and Administrator of Technical Programs" (page 04-4, item 5). These and related requirements are implemented by Subsections 4.2 and 4.10 through 4.13 and by Subsections 4.14 and 4.16 through 4.16.5 of procedure QAP-4.1. See, also, the response to Subcriterion 4.2, herein.

Requirements of part (b) of this subcriterion, verification of activities, are addressed on page 07-1 of the program, first paragraph, as follows. "NWPO evaluates contractor/subcontractor services and contractor compliance by means of periodic audits. NWPO reviews contractor surveillance reports of contractor/subcontractor activities. In accordance with technical procedures, NWPO may also conduct its own surveillances of contractor/subcontractor activities." See also page 07-1, second paragraph which states that "Contractor, subcontractor, and vendor/supplier activities are audited by the QA Manager and may be monitored by him/her or other NWPO

personnel." See, also, page 04-4, item 8, "The QA Manager audits any contractors' and subcontractors' certificates of conformance to the procurement documents, in accordance with procedure QAP-18.1. NWPO and contractors may perform surveillances of contractors' and subcontractors' activities and of vendors'/suppliers' promises. The QA Manager... receive(s) copies of surveillance reports and any corrective action is implemented per procedures QAP-15.1 and QAP-16.1." These requirements are implemented by procedure QAP-4.1, Subsections 4.21 and 4.22.

In a broader sense, NWPO verifies contractor and subcontractor activities by reading their output documents such as technical reports. Implementing procedures controlling generation of these documents always provide for transmittal of a copy to NWPO. See, for example, procedure QAP-3.2, "Technical Reports," Subsection 5.1. Any errors or deficiencies are corrected per a corrective action procedure (procedure QAP-16.1, Section 1.0 and page 16-1 of the program, third paragraph).

Concerning requirements of part (c) of the acceptance subcriterion, "Contractors and subcontractors are required to perform receiving inspections, as appropriate. NWPO is responsible for receiving inspections of materials and equipment purchased for its own (i.e., noncontractor) use" (page 07-1 of the program, second paragraph). This matter is also addressed on page 04-3 of the program, item 3f, and in procedure QAP-4.1, Figure 4.3-1, item 6. Compliance with this requirement is audited by the QA Manager.

"7.3 The organization providing materials, equipment, or services furnishes the following records to the purchaser:

a. Documentation that identifies the purchased service and the specific procurement requirements (e.g., codes, standards, and specifications) met.

b. Documentation identifying any procurement requirements that have not been met.

c. A description of those nonconformances from the procurement requirements dispositioned 'accept as is' or 'repair.'

The procedure for review and acceptance of these documents should be described in the purchaser's QA program."

Compliance Response

Item (a) of this acceptance criterion is addressed as follows. "Technical and QA responsibilities of contractors/subcontractors and vendors/suppliers are indicated in a procurement contract" (page 04-1 of the QA program, third paragraph). As shown on pages 04-2 and 04-3, item 3, a procurement document identifies the purchased service and specific procurement requirements (see, for example, Figure 4.3-1, item 3a, of procedure QAP-4.1, which specifies industry or government standards, codes, regulations, and guides to be followed). Signature of the contract in effect provides the documentation but in addition the contractor/subcontractor is required, on request, to furnish NWPO with a certificate of conformance to procurement documents (page 04-3 of the program, item 3g and Figure 4.3-1 of procedure QAP-4.1, item 7) as well as other documentation (i.e., information supplied

in the procurement document). The certificates are subject to review (verification) by audit (page 04-4 of the program, item 8, and procedure QAP-4.1, Subsection 4.21).

Concerning parts (b) and (c) of the subcriterion, NWPO has defined a nonconformance as a deficiency in a service, activity, procedure, item of equipment, etc. that renders the quality of the service, activity, etc. unacceptable or indeterminate rather than as a deviation from requirements of a procurement document that may or may not be acceptable, as implied by part (c). (See page 15-1 of the program, second paragraph, and the Glossary definition of nonconformance.)

By NWPO's definition, a nonconforming item can never be accepted "as is," as permitted in part (c); the only disposition is some form of corrective action. However, to accommodate legitimate procurement deviations that a contractor, subcontractor, or vendor/supplier may wish to propose, NWPO has introduced the term "authorized nonconformance" (page 15-1, third paragraph; Glossary definition), which allows NWPO to accept or reject such proposed changes. Authorized nonconformances are addressed in page 07-1 of the program, second paragraph and page 07-2, first paragraph; in page 04-4, item 9, and in procedure QCP-4.1, Subsections 4.17 through 4.20. In summary, the Principal Investigator informs the Administrator of Technical Programs and Project Manager, in writing, of any deviations in services or materials/equipment from procurement document requirements proposed by contractors, subcontractors or vendors/suppliers. The

Administrator of Technical Programs, QA Manager, and Project Manager consider the proposed deviation in light of criteria stated in procedure QAP-4.1. The Administrator of Technical Programs/QA Manager and, as appropriate, the Project Manager/Principal Investigator approve acceptable proposed changes which then become authorized nonconformances. The word "nonconformance" within the expression "authorized nonconformance" should be interpreted as authorized deviation or departure.

With reference to the final paragraph of the subcriterion, the required review and acceptance procedures are indicated in procedure QAP-4.1. See, also, responses to parts (a), (b), and (c) above.

"7.4 Suppliers' certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure they are valid and the results documented."

Compliance Response

The requirements of this acceptance criterion are addressed in the response to Subcriterion 7.2, part (b), above. Suppliers' (i.e., contractors', subcontractors', vendors') certificates of conformance, if any, are periodically audited (page 04-4 of the program, item 8; procedure QAP-4.1, Subsection 4.21). Results of the audit are documented in accordance with Section 18 of the QA program (page 18-2, fourth paragraph) and procedure QAP-18.1, "Audits," Subsection 4.11. For many NWPO-sponsored activities certificates of conformance are not required and need only be furnished at NWPO's request.

"7.5 In developing quality assurance requirements for data collection test equipment and other equipment, consideration should be given to whether proper performance of a test can be determined during or after testing (i.e., whether failure or malfunction of test equipment can be detected). Where no specific QA controls are found to be necessary, special quality/performance verification requirements shall be established and described in procedures governing the use of the equipment."

Compliance Response

Requirements of this subcriterion, as they apply to NWPO-sponsored activities, are addressed on page 07-2 of the QA program, second paragraph, as follows. "Equipment used for data collection is addressed in appropriate technical procedures. As needed, the technical procedures specify performance verification requirements."

Section 08 - Sample Identification and Control

"8. Activities related to sample Identification and Control are acceptable to the NRC staff if:

8.1 Controls are established and described to identify and control samples. The description should include organizational responsibilities."

Compliance Response

This acceptance criterion is addressed on page 08-1 of the QA program, second paragraph, in which technical procedures "...assign control and identification of samples to the appropriate contractors and subcontractors. Sampling is confined largely to materials of a geological or geotechnical nature such as rock, soil, and water." With reference to this subcriterion and to the subcriteria below, and to implementation of program requirements, see procedure QAP-2.2, "Preparation and Control of Technical Procedures," Figure 4.18-1, page 9, second paragraph, which requires that "...technical procedures conform to stated program requirements." Procedure QAP-2.2 also provides that the procedure controlling sample identification/control be cited by other technical procedures, as applicable (Figure 4.18-1, page 9, fifth paragraph). Sampling requirements are also specified by procurement contract documents. See procedure QAP-4.1, "Procurement Contract Control and Contractor/Subcontractor Qualification," Figure 4.3-1, item 3d, in which special handling, etc. requirements must be included in procurement documents.

Further details of controls are provided in responses to subcriteria below.

"8.2 Procedures are established which assure that identification is maintained either on the samples or their containers, or on records traceable thereto."

Compliance Response

"...(technical) procedures ensure that legible and permanent identification is maintained either on the samples or on their containers." (page 08-1 of the program, third paragraph).

"8.3 Identification of samples can be traced to the appropriate documentation such as drawings, specifications, purchase orders, drilling logs, test records, inspection documents, and nonconformance reports.

8.4 Correct identification of samples is verified and documented prior to release for use or analysis."

Compliance Response

These acceptance subcriteria are addressed in the fourth paragraph of page 08-1 of the program in which technical "...procedures provide for tracing of the samples to an appropriate document such as a drilling log or geologic map. Sample numbers and storage locations are placed on a list, together with necessary identification, and the list is sent to NWPO's Records Center in accordance with procedure QAP-17.1. Correct identification of samples is verified and documented prior to release of the samples for use or analysis. Samples of missing or uncertain identity are not used."

Section 09 - Control of Special Processes

"9. Activities related to Control of Special Processes are acceptable to the NRC staff if:

9.1 The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantageous, is provided.

9.2 Organizational responsibilities including those for the QA organization are described for qualfication of special processes, equipment, and personnel.

9.3 Procedures, equipment, and personnel associated with special processes are qualified and are in conformance with applicable codes, standards, QA procedures, and specifications. The QA organization is involved in the qualification activities to help assure they are satisfactorily performed.

9.4 Procedures are established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.

9.5 Qualifications records of procedures, equipment, and personnel associated with special processes are established and maintained."

Compliance Response

"There are no NWPO-sponsored activities that fall within the scope of the term 'special process' as understood by the NRC review plan or by NQA-1-1986 referenced in Section 00..." (page 09-1 of the program, first paragraph).

Section 10 - Inspections, Surveillance, and Monitoring

"10. Activities related to Inspection are acceptable to the NRC staff if:

10.1 The scope of the inspection program is described that indicates an effective inspection program has been established. Program procedures provide criteria for determining when inspections are required or define how and when inspections are performed. The QA organization participates in these functions."

Compliance Response

Considering the objectives of the activities governed by NWPO's QA Program as summarized, for example, on page 02-1 of the program, first paragraph, and page 03-1, first paragraph, Section 10 of the program has been expanded to address monitoring and surveillance activities as well as inspection. Recognizing that many NWPO-sponsored activities consist of observation of DOE work over which NWPO has no control it is best to consider monitoring, surveillance, and inspection together and to distinguish carefully between the terms. "For purposes of the program objectives, the terms 'surveillance' and 'monitoring' are identical, both meaning observation and documentation of an activity by a qualified, but nonparticipating and independent observer. Inspection is the documented examination or measurement of an activity or an item by a qualified and independent nonsupervisory person for compliance to specified requirements (page 10-1 of the program, first paragraph).

With reference to the scope of the inspection program, "Inspection is confined to NWPO-sponsored activities." (page 10-1 of the program, first paragraph), i.e., NWPO (or its contractors) could monitor a borehole drilled by a DOE contractor but could not inspect any sampling therefrom. As indicated in the second paragraph of page 10-1, activities such as drilling or sampling by (NWPO) subcontractors require inspection by contractor personnel. Further information on the scope of the inspection program is given in responses to subcriteria, below.

Concerning criteria of when inspection is required, "The decision of whether to inspect an activity or monitor it or rely entirely on auditing to verify satisfactory performance is made by NWPO's Administrator of Technical Programs, Executive Director and QA Manager and, as appropriate, by the contractor's Project Manager and Principal Investigator." (page 10-1, second paragraph). For contractors/subcontractors this can be done as part of procurement per procedure QAP-4.1 (page 10-1, second paragraph). Minimal criteria are listed on page 10-1. Contractors' and subcontractors' monitoring and inspection activities are authorized in procurement documents per procedure QAP-4.1. See Figure 4.3-1 of QAP-4.1, items 3c, 5a, and 9 for requirements that inspection activities be included in procurement documents, as appropriate, and that inspection activities be implemented by technical procedures. See Subsections 4.8, 4.12.4, 4.15, and 4.16.4 for the QA Manager's responsibilities in all of these matters.

With further respect to control of monitoring and inspection activities, "Surveillance/monitoring and inspection activities are... controlled by technical procedures" (page 10-1 of the program, third paragraph).

"10.2 Organizational responsibilities for inspection are described. Individuals performing inspections are part of the QA organization. For inspections requiring special expertise, other individuals may be used provided the independence of the inspection function is maintained."

Compliance Response

Requirements of this acceptance subcriterion are addressed as follows. "Surveillance/monitoring and inspection activities are... controlled by technical procedures. Persons conducting surveillances or inspections are NWPO or contractor/subcontractor staff members, as appropriate, and are appointed by the Administrator of Technical Programs, Project Manager, Principal Investigator, or others. The inspector or monitor is required to submit written reports to specified persons with copies to the QA Manager... Inspectors and monitors of NWPO and contractor/subcontractor activities are required to report apparent nonconformances... to the QA Manager for investigation and correction per procedures QAP-15.1 and QAP-16.1" (page 10-1 of the program, third paragraph, and page 10-2, first paragraph).

Inspectors are not a part of the QA organization because such an arrangement would not be feasible or desirable considering the size and nature of NWPO's and contractor's organizations. However, they maintain close contact with the QA Manager through the system of reports described immediately above.

"QA and technical procedures establish documented qualification requirements for inspectors and surveillance personnel" (page 10-2, second paragraph). Only qualified persons are allowed to perform inspections.

"10.3 A qualification program for inspectors is established and documented, and the qualifications and certifications or inspectors are kept current."

Compliance Response

This acceptance criterion is addressed on page 10-2 of the program, second paragraph, as follows. "QA and technical procedures establish documented qualification requirements for inspectors and surveillance personnel." The program makes no reference to formal certifications of inspectors because NWPO does not consider them necessary for the types of inspections performed by NWPO's contractors and subcontractors. Qualifications of inspectors/monitors are addressed by procedure QAP-1.1, "Position Titles, Position Descriptions, Employee Experience Records, and Qualification Statements" and in procedure QAP-4.1, Figure 4.3-1, item 2b, and Subsection 4.12, along with qualifications of other personnel. See, also, page 04-2 of the program, item 3b(2).

"10.4 Inspection procedures, instructions, or checklists provide for the following:

a. Identification of characteristics and activities to be inspected.

b. A description of the method of inspection.

c. Identification of the individuals or groups responsible for performing the inspection operation.

d. Acceptance and rejection criteria.

e. Identification of required procedures, drawings, and specifications and revisions.

f. Recording inspector or data recorder and the results of the inspection operation.

g. Specifying necessary measuring and test equipment including accuracy requirements."

Compliance Response

Requirements of this acceptance subcriterion are satisfied on page 10-2 of the QA program, second paragraph. All requirements must be included in technical procedures, as appropriate. For Subcriterion 10.4(f), see response to Subcriterion 10.6, below.

"10.5 Procedures include identification of mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector."

Compliance Response

This subcriterion is satisfied on page 10-2, second paragraph, item 7, which reads, "...(technical procedures provide for)... mandatory hold points beyond which work cannot proceed without inspection..."

"10.6 Inspection results are documented and evaluated, and their acceptability is determined by a responsible individual."

Compliance Response

Requirements of this subcriterion are satisfied on page 10-2 of the program, second paragraph, item 8, in which "...(technical procedures provide for)... evaluation of data and results and acceptance, as appropriate, and acceptance by the Principal Investigator, Project Manager, and Administrator of Technical Programs..." See, also, page 10-1, third paragraph and page 10-2, first paragraph, in which "The inspector or monitor is required to submit written reports... with copies to the... Administrator of Technical Programs, Project Manager... (and)... Principal Investigator..."

Section 11 - Test Control

"11. Activities related to Test Control are acceptable to the NRC staff if:

11.1 The description of the scope of the test control program indicates an effective test program has been established. Program procedures provide criteria for: (a) determining when a test is required or how and when testing activities are performed; and (b) the test program is conducted by trained or appropriately qualified personnel. The QA organization, as a minimum, audits these functions."

Compliance Response

There are no NWPO contractor or subcontractor activities that fit the definition of testing in NQA-1-1986, Supplement S-1,* or the implied definition of acceptance subcriteria 11.4a and e, i.e., Does an item meet certain prespecified requirements? In a strict sense, therefore, none of the acceptance subcriteria need be addressed. However, the test concept is relevant if used in a broader sense to designate research activities rather than "tests," as indicated below.

"In accordance with technical procedures and procurement documents, the contractors and subcontractors perform technical activities of an investigative nature including laboratory research. These investigations establish new methods, techniques, and data bases used in accomplishing NWPO's goals identified in the 'Statement of Quality Assurance

*NWPO does not include calibration in the definition of testing. See compliance responses to Criterion 12, herein.

Policy,' and in Sections 00 and 02 of the QA program..." (page 11-1 of the program, first paragraph). The scope of activities is indicated in procurement documents (page 04-2 of the program, item 3b, and procedure QAP-4.1, Figure 4.3-1).

With reference to item (a) of the subcriterion, determination of when an activity is required is accomplished through procurement contracts and technical procedures in much the same way as determination of when inspection is required. See compliance response to Subcriterion 10.1, above. In accordance with page 02-2 of the program, fourth paragraph and page 02-3, first and second paragraphs, methodologies of an experimental nature need not be specified in advance providing that data and methodologies are recorded as required by a special technical procedure. "Technical activities of a research nature are summarized in a technical report prepared in accordance with procedure QAP-3.2" (page 02-3 of the program, second paragraph) which is subject to review and approval.

With reference to item (b) of the subcriterion, qualifications of test personnel are controlled by procurement documents, per procedure QAP-4.1, and by employee qualification statements, per procedure QAP-1.1, in much the same way as for inspection/surveillance personnel. See compliance response to Subcriterion 10.3, above.

The QA Manager audits functions of Subcriterion 11.1 as part of his/her mandate to perform, "...planned and periodic audits of activities, procedures, documents,

records, and facilities to seek-out and evaluate objective evidence of compliance with the NWPO QA Program, implementing procedures, and procurement documents." (page 18-1 of the program, second paragraph).

"11.2 Test plans and procedures are reviewed in accordance with the verification requirements in Sections 3.7, 3.8, and 3.9."

Compliance Response

With reference to Subcriterion 11.2, "Review of activities and procedures... (is)... addressed in procedures that implement Sections 02, 03 and 04 of the program." (page 11-1 of the program, second paragraph). Activity plans and procedures are reviewed when the procurement document is reviewed (procedure QAP-4.1, Subsections 4.4 and 4.15). The contractor/subcontractor must also prepare implementing technical procedures (procedure QAP-4.1, Figure 4.3-1, item 9, and page 04-3 of the program, item 3i) which are also reviewed (procedure QAP-2.2, Subsection 4.13).

Concerning requirements of Subcriterion 3.7, reviews and reviewers of procurement documents are subject to the requirements indicated on page 03-2 of the program, second paragraph. See, also, procedure QAP-4.1, Subsection 4.2, "...the Executive Director shall assign... a(n) independent technical Reviewer... of the procurement document..." Likewise, "All technical procedures are reviewed by a technically qualified reviewer... in accordance with procedures QAP-2.1 and QAP-2.2" (page 02-1 of the program, second paragraph). See also the Glossary entry for Technical Reviewer which indicates that technical reviewers must be qualified by definition.

With reference to Subcriterion 3.8, "Peer review... (of the technical procedure)... if needed, shall be performed in accordance with the requirements delineated in procedure QAP-3.3" (procedure QAP-2.2, Subsection 4.19).

With reference to Subcriterion 3.9, Responsibilities of the Verifier, see response to Subcriterion 3.9 above.

"11.3 The potential sources of uncertainty and error in test plans and procedures, and parameters which must be controlled and measured to assure that tests are well-controlled, are identified."

Compliance Response

Requirements of this acceptance subcriterion are addressed on page 11-1 of the QA program, first paragraph, as follows. A controlling technical procedure must include "...identification of potential sources of uncertainty and error" (item 7). The intent of the subcriterion is met, also, by items 1 through 6. See, also, page 02-3 of the program, item 12.

"11.4 Test procedures or instructions provide for the following:

a. The requirements and acceptance limits contained in applicable documents, including precision and accuracy,

b. Instructions for performing the test,

c. Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage,

d. Mandatory inspection hold points (as required),

e. Acceptance and rejection criteria, including required levels of precision and accuracy,

f. Methods of data analysis,

g. Methods of documenting or recording test data and results,

h. Provisions for assuring test prerequisites have been met."

Compliance Response

The intent of the subcriterion requirements are responded to on page 11-1 of the program, first paragraph, and in implementing technical procedures. Items a and e have been omitted because they appear to imply that an item must meet certain prespecified requirements. See page 02-2 of the program, fourth paragraph, and page 02-3, first and second paragraphs; see response to Subcriterion 11.1, above.

"11.5 Test results are documented, evaluated, and their acceptability determined by a responsible individual or group as described in Section 3."

Compliance Response

Subcriterion 11.5 is numbered 11.3 in the NRC Review Plan. "Review of activities... and the evaluation and documentation of results are addressed in procedures that implement Sections 02, 03, and 04 of the program." (page 11-1 of the program, second paragraph). Refer, also, to page 02-2 of the program, fourth paragraph and page 02-3,

first and second paragraphs. See, as an example, procedure QAP-2.2 (page 9, fourth paragraph) which provides for data presentation and traceability.

As another example, the program requires that "Technical activities of a research nature are summarized in a technical report... in accordance with procedure QAP-3.2" (page 02-3 of the program, second paragraph). As specified in QAP-2.2, results may be presented in a summary and conclusions section, or elsewhere, or as drawings or tables (procedure QAP-3.2, Subsection 4.2.2). The report is reviewed for technical adequacy and input data verification by the Reviewer (Subsections 4.4 and 4.4.1) and also reviewed by the Approver (Subsection 4.8). The report is then sent to the Administrator of Technical Programs (Subsection 5.1) who may initiate peer review, if necessary (Subsection 4.13). All of these reviews contain some degree of evaluation. However, ultimate acceptability of the report from the standpoint of NWPO's objectives is the responsibility of NWPO.

Section 12 - Control of Measuring and Test Equipment

"12. Activities related to Control of Measuring and Test Equipment are acceptable to the NRC staff if:

12.1 The scope of the program for the control of measuring and test equipment is described and the types of equipment to be controlled are established."

Compliance Response

Requirements of this subcriterion are satisfied by the first paragraph of page 12-1 of the program as follows, "Requirements... are implemented by technical procedures prepared by the contractors or subcontractors... The equipment control procedures address all measuring and testing equipment in which faulty accuracy or precision can significantly affect data generated by the equipment and analyses based thereon. Examples of measuring and test equipment include analytical balances, pH meters, strain gauges, topographic survey instruments, and x-ray diffraction apparatus. Commercial-type off-the-shelf equipment, such as rulers or measuring tapes, are not included in the program."

Subcriterion 12.1 and subcriteria below are also addressed by procedure QAP-2.2, "Preparation and Control of Technical Procedures," which requires that, "Any procedure addressing calibration of measuring equipment must honor the requirements of Section 12 (of the program)" (Figure 4.18-1, page 9, second paragraph). Any technical procedure involving calibration must address calibration requirements

directly or by citation of other (controlling technical) procedures (Figure 4.18-1, page 9, fifth and ninth paragraphs).

"12.2 QA and other organizations' responsibilities are described for establishing, implementing, and assuring effectiveness of the calibration program."

Compliance Response

"As required by procurement contracts, the contractors and subcontractors are responsible for establishing procedures for the control of calibration and for the use of correct measuring and test equipment" (page 12-1 of the program, first paragraph; see, also, procedure QAP-4.1, Figure 4.3-1, item 3b and 9). Contractor/subcontractor compliance with procedures is, of course, mandatory (page 00-1 of the program, third paragraph).

The QA Manager reviews procurement documents and final contracts to ensure that QA requirements have been met (procedure QAP-4.1, Subsections 4.8, 4.12.4, 4.15, and 4.16.4, pages 04-2 and 04-4 of the program, items 2 and 5). QA requirements include the requirement for calibration control referred to and referenced above. Also, technical procedures governing calibration activities are subject to technical review and review by the QA Manager (page 02-1 of the program, second paragraph, page 02-2, first paragraph).

The QA Manager "...performs... audits... to seek-out and evaluate objective evidence of compliance with the NWPO QA Program, implementing procedures, and procurement documents... Quality of work audited is a major audit goal"

(page 18-1 of the program, second paragraph). In addition, NWPO and contractors may monitor contractors' and subcontractors' activities (including calibration control) with the QA Manager receiving copies of the surveillance/monitoring reports (page 10-1 of the program, third paragraph and 10-2, first paragraph; page 07-1 of the program, first paragraph; and procedure QAP-4.1, Subsection 4.22).

"12.3 Procedures are established and described for calibration (technique and frequency), maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) used for measurement, inspection, and monitoring. The review and documented concurrence of these functions is identified."

Compliance Response

The requirements of this acceptance subcriterion are addressed as follows. "The controlling technical procedures are required to address... (1) a description of calibration techniques and frequencies of calibration... (2) maintenance and control of equipment used for measurement, testing, inspection, and monitoring, and documentation thereof..." (page 12-1, second paragraph).

"12.4 Measuring and test equipment is labeled, tagged or otherwise documented to indicate due date of the next calibration and to provide traceability to calibration test data."

Compliance Response

This subcriterion is addressed on page 12-1 of the program, second paragraph, item 4, which states that, "...controlling technical procedures are required to address ...documentation of date of next scheduled calibration of measuring and testing equipment so as to provide traceability to calibration test data."

"12.5 Measuring and test equipment is calibrated at specified intervals based on required accuracy, precision, purpose, degree of usage, stability, characteristics, and other conditions which could affect measurement."

Compliance Response

This subcriterion is addressed on page 12-1 of the program, second paragraph, item 3, which states that, "...controlling technical procedures are required to address ...specification of calibration intervals, based on required accuracy, precision, purpose, degree of usage, stability characteristics, and other conditions that could affect measurements..."

"12.6 Calibration standards are traceable to nationally recognized standards. Where national standards do not exist, provisions are established to document acceptability of the calibration standard used."

Compliance Response

The requirements of this acceptance subcriterion are satisfied on page 12-1, third paragraph, which states that "The technical procedure(s)... includes instructions that require traceability of calibration

standards to nationally recognized standards or provision for documentation of acceptability of the calibration standard used where recognized standards do not exist."

"12.7 When measuring and test equipment is found to be out of calibration, evaluations are made and documented to determine the validity and acceptability of measurements performed since the last calibration. Inspections or tests are repeated on items determined to be suspect."

Compliance Response

Requirements of this acceptance subcriterion are satisfied on page 12-2 of the program, first paragraph, which reads, "Any measuring or testing equipment found to be out of calibration after data acquired with the equipment have been incorporated into output or input/support documents, is reported to the QA Manager for appropriate action as prescribed by Sections 15 and 16 of the program and by procedures QAP-15.1 and QAP-16.1. The technical procedure mandates documented evaluations to determine the validity and acceptability of measurements performed since the last calibration. As necessary, measurements or tests of suspect items are repeated. Out-of-calibration equipment is marked or tagged as such."

Section 13 - Sample Handling, Storage, and Shipping

"13. Activities related to Sample Handling, Storage, and Shipping are acceptable to the NRC staff if:

13.1 Sampling, handling, preservation, storage, packaging, and shipping requirements are established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions.

13.2 Procedures are established and described to control sample handling, storage, packaging, and shipping in accordance with design and procurement requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity."

Compliance Response

Requirements of these subcriteria are satisfied by page 13-1 of the program, second paragraph and page 13-2, first paragraph, as follows. "The contractors and subcontractors are responsible for custody, handling, preservation, storage, packaging, shipping, and retrieval of samples acquired through their own activities, or from the DOE, or others, in accordance with the following requirements as detailed by procurement documents and implementing technical procedures:

1. Activities are performed by trained, qualified individuals in accordance with predetermined work procedures and instructions, as appropriate.

2. Samples are stored under conditions of adequate security. A reference collection of samples is stored permanently, as permitted by the properties

of the sample. As appropriate, analyzed samples are stored separately.

3. Samples are appropriately identified and are protected from damage, loss, or physical deterioration from temperature, humidity, or other environmental agents. As necessary, special handling, equipment, packaging, or controlled environments are provided.

4. Sample location and storage documentation is submitted to the QA Manager for retention in NWPO's Records Center in accordance with procedure QAP-17.1.

5. Samples are traceable from initial acquisition through final disposition. By use of sample transmittal forms, record of custody forms, or equivalent forms, physical location and custody of samples is known at all times. Any interface relations between multiple organizations concerning sample custody and management are clearly described.

See procedure QAP-2.2, Figure 4.18-1, page 9, second paragraph, reading that, "...any procedure addressing sample handling... must honor the stated requirements of Section 13 of the NWPO QA Program." See, also, procedure QAP-4.1, Figure 4.3-1, item 3d, which states that the procurement document must include detailed requirements for "special sample-handling, packaging, shipping and storage..." See, also, the response to Subcriterion 8.1 for further explanation of how the program requirements are implemented by technical and QA procedures and by procurement documents.

Section 14 - Inspection, Test and Operating Status

"14. Activities related to Inspection, Test and Operating Status are acceptable to the NRC staff if:

14.1 Procedures are established to indicate by the use of markings the status of inspections and tests on individual items."

Compliance Response

As stated on page 14-1 of the program, first paragraph, "Neither NWPO nor its contractors or subcontractors perform... activities controlled by Criterion 14 of 10CFR50, Appendix B or by the NRC Review Plan..."

See page 10-2 of the program, second paragraph, "...procedures provide for the following documentation as applicable and feasible... 9) a description of the method for controlling the application and removal of status indicators."

Section 15 - Nonconformances

"15. Activities related to Nonconformances are acceptable to the NRC staff if:

15.1 Procedures are established for identifying, documenting, tracking, segregating, reviewing, dispositioning, and notifying affected organizations of nonconforming items and activities. The procedures identify individuals authorized to dispose of and close out nonconformances."

Compliance Response

Requirements of this acceptance subcriterion are addressed principally by Section 15 of the program, "Nonconformances" and by procedure QAP-15.1, "Nonconformances," but are also considered by other program sections and QA procedures as indicated below. See the definition of "nonconformance" of page 15-1 of the program, second paragraph, and in the Glossary noting that a nonconforming item or activity is unacceptable by definition.

With reference to identifying nonconformances, "The QA Manager shall be made aware of nonconformances... by means... (of)... audits conducted by the QA Manager... (per procedure QAP-18.1)... (by)... reports of surveillances conducted by or for NWPO... direct mandatory notifications from inspector or other NWPO, contractor/subcontractor, or vendor/supplier personnel observing apparent nonconformances... (or by)... other means." (procedure QAP-15.1, Subsection 4.1). Concerning nonconformances reported from audits, a nonconformance is an audit finding that satisfies the definition of nonconformance and is processed in

accordance with procedure QAP-15.1 (procedure QAP-18.1, "Audits," Subsection 4.13.3). See procedure QAP-18.1, Subsection 4.9 for details of identification of nonconformances by audits and procedure QAP-15.1, Subsections 4.3 through 4.5 and Subsection 4.7 for details of identification of nonconformances arising from surveillances or reported by individuals.

With reference to documenting of nonconformances, "The QA Manager... (initiates)... a nonconformance report... (NCR)... immediately upon notification of a nonconformance or apparent nonconformance" (procedure QAP-15.1, Subsection 4.10). Among other things, the NCR identifies the NCR number and the date, origin, description, corrective action, and close-out of the nonconformance; also, an indication whether nonconformance is a potential significant condition adverse to quality (Subsection 4.10). Closed-out NCRs are filed in the NWPO QA Records Center (Subsections 5.1 and 5.1.1). See Subsection 4.10, items 1 through 10, for further information regarding NCRs. See procedure QAP-16.1, "Corrective Action," Subsection 4.2 for details concerning documentation of corrective action and close-outs on NCRs.

Tracking of nonconformances is addressed in procedure QAP-15.1, Subsections 4.19 and 4.20, which govern tracking of NCRs. "The QA Manager shall initiate and maintain an NCR tracking log to facilitate monitoring and closing-out of nonconformances in a timely manner" (Subsection 4.19). The log includes date of required response to the NCR and date of final close-out.

Segregation of nonconforming items is addressed in procedure QAP-15.1, Subsection 4.13, which reads, "All nonconforming items shall be segregated if practical."

Concerning review of nonconformances, "The QA Manager shall determine if any nonconformance is a potential significant condition adverse to quality (SCAQ)" (procedure QAP-15.1, Subsection 4.6). The QA Manager then confers with the Administrator of Technical Programs, Project Manager, Principal Investigator... to establish whether a significant condition adverse to quality exists" (procedure QAP-16.1, Subsection 4.10). As discussed above, the QA Manager provides for tracking of NCRs (Subsection 4.19). NCR trend analyses are sent to the Executive Director and others, as needed. (procedure QAP-16.1, Subsection 4.23).

Considering another aspect of review, deviations from requirements of procurement documents that contractors or subcontractors wish to propose are reviewed by the Administrator of Technical Programs/QA Manager and others, as needed, and if approved, are classified as authorized nonconformances. See definition of authorized nonconformance of page 15-1 of the program, third paragraph; see compliance response to Subcriterion 7.3(b)(c); see discussion of dispositioning, below.

With reference to dispositioning, in the context of NWPO's definition of nonconformance, i.e., something that renders the quality of an item/activity unacceptable or indeterminate, the only disposition of a nonconformance is corrective action. Corrective action is accomplished per procedures QAP-16.1 and QAP-15.1 as shown, for example, by Figure 8.0-1 of procedure QAP-16.1.

To accommodate contractors' requests for deviations of items or services from procurement requirements, the program and procedures include a mechanism for acceptance or rejection

of the requests. "The Administrator of Technical Programs, QA Manager and as appropriate, the Project Manager/Principal Investigator... approve in writing acceptable (i.e., authorized) deviations which... then become authorized nonconformances." (procedure QAP-4.1, Subsection 4.19). See, also, page 04-4 of the program, item 9, and the definition of "authorized nonconformance" on page 15-1 of the program, third paragraph.

Notifying affected organizations of nonconforming items and activities is specified in procedure QAP-15.1, Subsections 4.11 and 4.12. The Administrator of Technical Programs or Project Manager/Principal Investigator, as appropriate, ensure that nonconforming items are clearly identified and that affected individuals are informed of nonconforming activities immediately by memo with a copy to the QA Manager. In addition, "The QA Manager shall ensure that the appropriate Responsible Individual receives a copy of the closed-out NCR with all attached documentation." (procedure QAP-15.1, Subsection 5.3). Distribution of authorized nonconformance documentation is covered in procedure QAP-4.1, Subsection 5.1.

With respect to disposition and close-out of nonconformances, "After the QA Manager has verified that corrective action... is complete... (per procedure QAP-16.1), the QA Manager shall close-out the nonconformance by dating and signing the NCR." (procedure QAP-15.1, Subsection 4.17). Disposition of authorized nonconformances is discussed above in paragraphs responding to this subcriterion.

"15.2 QA responsibilities related to nonconformance control are described."

Compliance Response

This subcriterion is addressed in the response to Subcriterion 15.1, above. In brief and as indicated in procedure QAP-15.1, the QA Manager identifies and investigates nonconformances (Subsections 4.1 through 4.7), initiates and maintains nonconformance reports (NCRs) (Subsection 4.10), informs affected persons of nonconforming items/activities (Subsections 4.11 and 4.12), closes-out nonconformances (Subsection 4.17), and maintains a tracking log (Subsections 4.19 and 4.20). The QA Manager also approves authorized nonconformances (procedure QAP-4.1, Subsection 4.19) and conducts trend analyses of NCRs (procedure QAP-16.1, Subsection 4.23).

"15.3 Documentation identifies and describes the nonconformance, dispositions the nonconformance, and includes signature approval of the disposition."

Compliance Response

This acceptance subcriterion is responded to in the response to Subcriterion 15.1, above. In brief, nonconformances are identified and described in nonconformance reports (procedure QAP-15.1, Subsection 4.10) and authorized nonconformances are identified and described in written communications prepared by the Principal Investigator (procedure QAP-4.1, Subsection 4.17).

With respect to disposition, the QA Manager closes-out a nonconformance by signing the NCR (procedure QAP-15.1, Subsection 4.17). In the context of NWPO's definition of nonconformance, this is the only disposition possible - corrective action. In the case of authorized nonconformances (i.e., deviations approved in advance), approval is indicated in writing (procedure QAP-4.1, Subsection 4.19).

"15.4 Nonconformance reports are periodically analyzed by the QA organization to show quality trends and to help identify root causes of non-conformances, and the significant results are reported to upper management for review and assessment."

Compliance Response

This requirement is satisfied in procedure QAP-16.1, Subsections 4.23 and 4.24, which require the QA Manager to perform a documented trend analyses of nonconformances and to report adverse trends to the Executive Director.

Section 16 - Corrective Action

"16. Activities related to Corrective Action are acceptable to the NRC staff if:

16.1 Procedures are established indicating an effective corrective action program has been established. The QA organization reviews and documents concurrence with the procedures."

Compliance Response

Corrective action resulting from nonconformances (including those determined from audit findings) is conducted in accordance with procedure QAP-16.1, "Corrective Action" and documented on nonconformance reports (NCRs) per procedure QAP-15.1, "Nonconformances." Corrective action resulting from significant conditions adverse to quality (SCAQs) is conducted in accordance with procedure QAP-16.1 and documented on corrective action reports (CARs). Corrective action resulting from audit observations or from audit findings not classified as nonconformances is conducted in accordance with procedure QAP-18.1, "Audits" and documented on a written response to the audit report. See Figure 8.0-1 of procedure QAP-16.1 for an overview of corrective action for nonconformances and SCAQs. See compliance response to Subcriterion 2.7b for a discussion of corrective action resulting from management assessment of the QA program (procedure QAP-2.4).

Procedures QAP-15.1, QAP-16.1 and QAP-18.1 are quality assurance (QA) procedures and are therefore approved by the QA Manager. "The QA Manager approves all QA

procedures..." (page 02-2 of the program, first paragraph). "The QA Manager shall sign the affected part of the QA manual (i.e., QA procedure) as approver..." (procedure QAP-2.1, Subsection 4.5).

In corrective action for nonconformances, the QA Manager prepares an NCR per procedure QAP-15.1 and forwards it to the Administrator of Technical Programs or to the Project Manager, Principal Investigator or other Responsible Individual (procedure QAP-16.1, Subsections 4.3 and 4.4). The Administrator of Technical Programs, Project Manager, Principal Investigator or others consult with the QA Manager, formulate a corrective action plan, document it on the NCR, and perform the corrective action (Subsections 4.3 and 4.4). "The QA Manager approves all corrective action plans prior to their implementation" (Subsection 4.6). Dates for completion of corrective action are set in accordance with page 16-1 of the program, third paragraph, which requires correction of nonconformances in a timely manner.

Concerning significant conditions adverse to quality, the QA Manager evaluates nonconformances, identifies potential SCAQs per procedure QAP-15.1, and consults with the Administrator of Technical Programs, Project Manager, Principal Investigator and others as needed (procedure QAP-16.1, Subsection 4.10). If the potential SCAQ is indeed a SCAQ, the QA Manager initiates a corrective action report (CAR) and forwards a copy to the Responsible Individual as soon as feasible (Subsections 4.10.1, 4.11, 4.12). The Responsible

Individual consults with the QA Manager and others, as needed, formulates a corrective action plan, documents it on the CAR, and proceeds with the corrective action (Subsection 4.14). "The QA Manager shall approve all corrective action plans prior to implementation" (Subsection 4.14.2). Completion dates for corrective action are set in accordance with page 16-1 of the program, third paragraph, which requires completion of corrective actions as soon as practical.

In the case of audit observations and audit findings not classified as nonconformances, the QA Manager conducts a post-audit conference to present audit findings/observations to the Responsible Individual audited (procedure QAP-18.1, Subsection 4.10). The QA Manager then documents the findings/observations in an audit report and sends the report to the Responsible Individual (Subsections 4.11 and 4.12). The Responsible Individual audited confers with the QA Manager and others, as needed, formulates a written response to the audit report and proceeds with corrective action as appropriate (Subsection 4.14). "The QA Manager shall approve any corrective action to be taken." (Subsection 4.14.1).

"16.2 Corrective action is documented and initiated following a nonconformance to preclude recurrence. The QA organization is involved in documented concurrence of the adequacy of corrective action to assure that QA requirements are satisfied."

Compliance Response

Requirements of this subcriterion are largely answered in the response to Subcriterion 16.1, above. Inasmuch as follow-up action and verification of corrective

action by the QA organization are addressed in Subcriterion 16.3, below, we infer that the term "corrective action" of Subcriterion 16.2 means corrective action plan.

Documentation of corrective action plans for nonconformances and QA involvement therein are addressed in procedure QAP-15.1, Subsection 4.10, and procedure QAP-16.1, Subsections 4.3 and 4.4 through 4.6. Corrective action is documented on an NCR. "Corrective action plans shall address the root cause(s) of the nonconformance..." (Subsection 4.5). Subsections 4.3 and 4.4 of procedure QAP-16.1 require the corrective action plan to correct the nonconformance and to preclude recurrence of the nonconformance. Similar requirements apply to significant conditions adverse to quality (procedure QAP-16.1, Subsections 4.11 through 4.14.2) and to audit findings/observations (procedure QAP-18.1, Subsections 4.11 and 4.14 through 4.14.2).

"16.3 Follow-up action is taken by the QA organization to verify proper implementation of corrective action and to close out the corrective action in a timely manner."

Compliance Response

With reference to nonconformances, requirements of this acceptance subcriterion are answered in procedure QAP-16.1, Subsections 4.7 and 4.7.1, which state that, "The QA Manager... shall verify and document that... corrective action for the nonconformance has been satisfactorily and effectively implemented.

Verification may be accomplished by a special follow-up audit scheduled and performed per procedure QAP-18.1, 'Audits.' If corrective action has been satisfactorily and effectively implemented, the QA Manager shall so indicate this by his/her dated signature on the NCR closing-out the nonconformance and the NCR."

With respect to significant conditions adverse to quality, the procedure is similar except that a special follow-up audit is mandatory and that close-out is documented on the corrective action report. See procedure QAP-16.1, Subsections 4.15 and 4.15.1.

Concerning audit observations and audit findings not classified as nonconformances, "The QA Manager... shall verify and document that corrective action has been satisfactorily implemented. Verification may be accomplished by a special follow-up audit..." (procedure QAP-18.1, Subsection 4.15). "If corrective action for the audit has been satisfactorily... implemented, the QA Manager shall so indicate this by his/her dated signature on the audit report response... closing out the audit..." (procedure QAP-18.1, Subsection 4.15.1).

Scheduling of corrective action verification for nonconformances and SCAQs is guided by page 16-1 of the program, third paragraph, which states that, "Nonconformances are corrected in a timely manner. Significant conditions adverse to quality are corrected as soon as practical."

"16.4 Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken to preclude repetition are documented and reported to immediate management and upper levels of management for review and assessment."

Compliance Response

Requirements of this acceptance subcriterion are addressed in procedure QAP-16.1, "Corrective Action." "The QA Manager shall ensure that the Executive Director and Administrator of Technical Programs, as well as the Project Manager... (and)... Principal Investigator... receive a copy of the closed-out CAR with attached documentation as needed" (Subsection 5.3). CARs include the "...Nature and description of the significant condition adverse to quality..." and "...Nature of corrective action plan..." (Subsection 4.11). "Corrective action plans... address the root cause(s) of the SCAQ... any required remedial action to be taken, and action necessary to prevent the recurrence of the condition." (Subsection 4.14.1). With respect to verification that corrective action has been performed, the QA Manager conducts a special follow-up audit per procedure QAP-18.1 (procedure QAP-16.1, Subsection 4.15). These audits are documented in audit reports which are distributed to the Executive Director, Administrator of Technical Programs, Project Managers, Principal Investigators, and others (procedure QAP-18.1, Subsections 4.11 and 5.2).

The following are additional ways by which management is informed of SCAQs, corrective action, etc. The QA Manager consults with the Administrator of Technical Programs,

Project Managers, and Principal Investigator to determine if a SCAQ exists (procedure QAP-16.1, Subsection 4.10) and the Executive Director considers each SCAQ for a possible stop-work order (Subsection 4.10.1). The Executive Director also receives reports of any adverse trends in SCAQs (Subsection 4.23).

Section 17 - Quality Assurance Records

"17. Activities related to Quality Assurance Records are acceptable to the NRC staff if:

17.1 The scope of the records program is described. QA records include geotechnical samples and data; results of reviews; inspections; tests, audits, and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports; design review reports; peer review reports; nonconformance reports; and corrective action reports."

Compliance Response

The scope of the records program is given on page 17-1 of the program, first through fourth paragraphs, on page 17-2, first paragraph, and in procedure QAP-17.1, "Quality Assurance Records," Section 1.0. As stated in the program, "...the... program addresses collection, processing, filing, storage, and retrieval of quality assurance records generated by NWPO and its contractors, subcontractors and vendors/suppliers. Quality assurance records are defined as completed documents, accepted for the NWPO Records Center per stated requirements, that furnish evidence of the quality of items and/or activities significant to NWPO's objectives." (page 17-1, first paragraph).

Also, "...records can be 'paper' items, such as technical reports, procurement contracts, or photographs, or can be other items, such as films or computer or video tapes... Output documents, such as

technical procedures, procurement documents, or technical reports, for which implementing procedures require formal review and approval, are not considered complete until they have been dated and until they have been signed by the approver or reviewer and approver, as appropriate. Input/support documents, such as field notes or laboratory data books, for which formal review and approval may not be required, are not considered complete without dated evidence of verification and completeness, as specified by implementing procedures." (page 17-1, second paragraph).

Examples of types of quality assurance records are given on pages 17-1 and 17-2 of the program and in implementing procedures. These examples are meant to satisfy the intent of acceptance Subcriterion 17.1 as applicable to NWPO-sponsored activities. "However, geotechnical or other samples, such as rock cores or water... are not classified as records..." (page 17-1 of the program, second paragraph). Instead, NWPO has found it convenient to assign identification, storage and retrieval of geotechnical samples to the appropriate contractor or subcontractor in accordance with technical procedures (see Section 13 of the QA program and the response to Criterion 13, herein). "Sample location and storage documentation is submitted to the QA Manager for retention in NWPO's Records Center in accordance with procedure QAP-17.1." (page 13-1 of the QA program, second paragraph, item 4). This documentation is considered a QA record (page 17-2 of the program, item 15). Contractors' and subcontractors' activities relating to QA records are subject to audit by the QA Manager.

"17.2 QA and other organizations are identified and their responsibilities are described for the definition and implementation of activities related to QA records."

Compliance Response

Responsibilities of the QA and other organizations are defined on page 17-2 of the QA program, second paragraph, on page 17-3, first, third, and fifth paragraphs, in procedure QAP-17.1, "Quality Assurance Records," and in technical procedures. In general, the contractors/subcontractors are responsible for collection, identification, acceptability, marking and submittal to the NWPO Records Center of their own and vendors'/suppliers' records, and the Administrator of Technical Programs and QA Manager are similarly responsible for NWPO-generated records, for records generated by NWPO's direct vendors/suppliers, and for certain other records (page 17-2 of the program, second paragraph; procedure QAP-17.1, Subsections 4.1 through 4.3.1). "Records must be legible, of reproducible quality, physically durable (e.g., of good quality paper) and complete... Records must include the name of the record-generating organization, identification as an NWPO record, identification of record type... record title, record revision designation and/or completion date, as appropriate, and the category file index designation as specified by controlling procedure QAP-6.1." (page 17-3, second paragraph).

"The QA Manager is in charge of an NWPO Records Center and ensures that properly marked NWPO, contractor/subcontractor and vendor/supplier records are correctly processed and... filed in the Center under his/her control. All records are

permanently retained... the QA Manager maintains a stored records index..." (page 17-3 of the program, third paragraph; see procedure QAP-17.1, Subsections 4.5 through 4.8, for details). The QA Manager also processes requests for record retrieval (page 17-3 of the program, fifth paragraph and procedure QAP-17.1, Subsections 4.9 through 4.11).

"17.3 Inspection and test records contain the following where applicable:

a. A description of the type of observation.
b. The date and results of the inspection or test.
c. Information related to conditions adverse to quality.
d. Inspector or data recorder identification.
e. Evidence as to the acceptability of the results.
f. Action taken to resolve any discrepancies noted."

Compliance Response

Requirements of this subcriterion with respect to inspection are addressed on page 10-2 of the QA program, second paragraph, in which all listed items of the subcriterion must be documented in accordance with a technical procedure. Subcriterion 17.3a is addressed in item 1; 17.3b in items 3 and 8, 17.3d in item 3; and 17.3e in item 8. With respect to subcriteria 17c and 17f, "Inspectors of... NWPO and contractor/subcontractor activities are required to report apparent nonconformances... to the QA Manager for investigation and correction per procedures QAP-15.1 and QAP-16.1." (page 10-2 of the program, first paragraph). Inspection reports, nonconformance reports, and

corrective action reports are then included among the documents that must be submitted to the NWPO Records Center (page 17-2 of the QA program, items 4 and 5). See, also, procedures QAP-15.1 and QAP-16.1 in general, and Figure 8.0-1 of QAP-16.1 noting that the reporting individual (upper left box) includes then inspector (QAP-15.1, Subsection 4.1).

With respect to test records, see response to Subcriterion 11.1, above, which explains that NWPO-sponsored activities do not include tests as they are defined by the NRC review criteria. Page 11-1 of the program, first paragraph, provides for adequate documentation of NWPO-sponsored technical activities of an investigative or research nature. Technical activities are controlled by technical procedures and technical procedures are controlled by procedure QAP-2.2, "Preparation and Control of Technical Procedures," which mandates that technical procedures adhere to specified minimum documentation standards (Figure 4.18-1, page 8, lines 18 through 21 and page 9, fourth paragraph). See, also, page 02-3 of the program, first paragraph, for documentation requirements of technical activities of a research or experimental nature.

"17.4 Suitable facilities for the storage of records are described and utilized."

Compliance Response

All records submitted by NWPO and its contractors, subcontractors, and vendors/suppliers are retained in a single records center controlled by the QA Manager.

"Records are stored in metal file cabinets located in the NWPO Records Center. Records are firmly attached in binders, folders, or envelopes, and are protected from moisture and from excessive heat or pressure. Sensitive records, such as film negatives or computer tapes, receive special protection from hazards such as excessive light, magnetic fields, or stacking. The QA Manager controls access to the file cabinets" (page 17-3 of the program, fourth paragraph). See, also, procedure QAP-17.1, "Quality Assurance Records," Subsections 4.5.1 through 4.5.3.

Section 18 - Audits

"18. Activities related to Audits are acceptable to the NRC staff if:

18.1 Internal and external audits to assure that procedures and activities comply with the overall QA program are performed by DOE and its contractors. DOE should perform audits of the prime contractor and representative subcontractors, consultants, vendors, and laboratories to assess the effectiveness of the prime contractor's audit program."

Compliance Response

In its present wording this subcriterion is not entirely applicable to NWPO's QA Program or organization. In the context of NWPO's QA Program and its relationship to its contractors/subcontractors and vendors/suppliers, references to internal and external audits and to contractors' audit programs are not relevant. "NWPO is responsible for quality assurance (and)... for... audit of NWPO's, and contractors'/subcontractors' activities and vendors/suppliers..." (page 01-7 of the program, fourth paragraph). "The (NWPO) program is the sole QA program governing activities of NWPO and its contractors/subcontractors, and vendors/suppliers working as an integrated organization" (page 02-1 of the program, first paragraph). "There are no separate contractor or subcontractor QA manuals that govern NWPO-sponsored activities" (page 00-1 of the program, third paragraph). "There are no contractors', subcontractors', or vendors'/suppliers' audit organizations that audit NWPO-sponsored activities" (page 18-1 of the QA program, first paragraph).

With the above reservations, NWPO's QA Program is in compliance with the requirements of the acceptance criterion. "The QA Manager performs planned and periodic audits of activities, procedures, documents, records, and facilities to seek-out and evaluate objective evidence of compliance with the NWPO QA Program, implementing procedures, and procurement documents... As required by procedure QAP-18.1, all parts of NWPO's and of contractors,' subcontractors,' and vendors'/suppliers' organizations engaging in significant activities within the scope of the NWPO QA Program are subject to audit" (page 18-1 of the QA program, second paragraph). "All significant aspects of the program and participating organizations and their activities are audited" (page 18-2 of the program, first paragraph). "The (audit) schedule shall ensure that all significant aspects of the program and all participating organizations and their activities, documents, records, and facilities are adequately audited" (procedure QAP-18.1, "Audits," Subsection 4.1).

"18.2 An audit plan is prepared identifying audits to be performed, their frequencies, and schedules. Audits are regularly scheduled based upon the status and safety importance of the activities being performed and are initiated early enough to assure effective QA."

Compliance Response

The NWPO QA Program and procedures are in compliance with the requirements of this acceptance subcriterion. However, the term "schedule" is substituted for the term "plan," plan being reserved for instructions

concerning a particular audit. "Audits are conducted according to a predetermined schedule identifying audits to be performed, and their frequencies and dates. As specified by procedure QAP-18.1, there are also required and scheduled special audits to verify (follow-up) implementation of corrective action arising from significant conditions adverse to quality (SCAQs). As needed, there are also follow-up audits in response to nonconformances, findings, and observations, also special audits in response to requests, or as the QA Manager may deem necessary." (page 18-1 of the program, second paragraph). See procedure QAP-18.1, "Audits," Subsections 4.1 through 4.2, 4.15, and 4.16 through 4.16.3, for details.

With reference to scheduling, "Scheduling and timing of audits depends on the nature and duration of the activity being audited" (page 18-2 of the program, first paragraph). See, also, procedure QAP-18.1, Subsection 4.1. The term "safety importance of the activities" is not directly relevant to NWPO's goals and objectives. NWPO considers all NWPO-sponsored activities equally significant for purposes of QA control. The frequency and scope of audits depend on the nature and duration of activities being audited. See responses to Subcriteria 1.8, 2.1 and 2.5, above.

With reference to audit plans, "An audit plan is developed for each audit indicating the audit scope, the activities to be audited, the applicable documents and requirements, the audit schedule, and the names of

auditors" (page 18-2 of the QA program, third paragraph). See procedure QAP-18.1, Subsections 4.3 through 4.6 for further details.

"18.3 Audits include an objective evaluation of the quality-related practices, procedures, instructions, activities, and items and the review of documents and records to ensure that the QA program is effective and properly implemented."

Compliance Response

As indicated on page 18-1 of the QA program, second paragraph, "The QA Manager performs planned and periodic audits of activities, procedures, documents, records, and facilities to seek-out and evaluate objective evidence of compliance with the NWPO QA Program, implementing procedures, and procurement documents. He/she also uses audits to evaluate the effectiveness and implementation of all significant aspects of the program and implementing procedures... Quality of work audited is a major audit goal." As stated in procedure QAP-18.1, Subsection 4.9, "The QA Manager and Technical Auditor(s), if any, shall seek out, examine, and evaluate documents and other objective evidence verifying that NWPO, contractor, subcontractor, and vendor/supplier activities are being performed and controlled in compliance with the NWPO QA Program, implementing procedures, and procurement documents, that the QA program and procedures are effective in establishing quality of work, and that corrective action is being implemented."

"18.4 Audit data are analyzed by the QA organization and the results are reported to responsible management for review, assessment, and appropriate action."

Compliance Response

This acceptance subcriterion is addressed on page 18-3 of the program, second paragraph, which states that, "The QA Manager is... required to perform a trend analysis of audit findings and observations and to report any adverse trends to the Executive Director." Further information is provided in procedure QAP-18.1 which requires that, "...Trend analysis shall be performed, as a minimum, semiannually..." (Subsection 4.18) and that, "Trend analysis of audit findings classified as nonconformances shall be included with the NCR/CAR trend analysis of procedure QAP-16.1." (Subsection 4.18.1). See, also, procedure QAP-18.1, Subsections 4.13 through 4.13.3.

Audit results are also reported to management by means of audit reports. See response to Subcriterion 18.7, below.

"18.5 Audits are performed in accordance with pre-established written procedures or checklists and conducted by trained personnel having no direct responsibilities in the areas being audited."

Compliance Response

Requirements of this acceptance subcriterion are satisfied as follows. "Audits are performed in accordance with written checklists..." (page 18-2 of the program, third paragraph). "For each audit, the QA Manager shall... prepare a checklist comprised of questions to be used in the audit. The purpose of this checklist is to ensure depth and continuity of the

audit and to aid in the evaluation of objective evidence of compliance with requirements of the QA program and procedures" (procedure QAP-18.1, "Audits," Subsection 4.5).

With further reference to subcriteria requirements, "The QA Manager, who is a certified Lead Auditor, is responsible for all audits. All audits are performed by the QA Manager... with the aid of qualified independent Technical Auditors, as needed" (page 18-1 of the program, first paragraph). "All audits shall be led and performed by the QA Manager, who shall be a certified Lead Auditor. The QA Manager may be assisted by an independent qualified Technical Auditor(s) as necessary" (procedure QAP-18.1, Subsection 4.3). See page 01-9 of the program, third paragraph, for a list of minimum requirements for the position of QA Manager including certification as a Lead Auditor. With respect to independence, "The QA Manager... reports directly to the Executive Director... (and)... devotes his/her time exclusively to quality assurance functions" (page 01-7 of the program, second paragraph).

Activities of the QA Manager are assessed by the Executive Director per procedure QAP-2.4.

"18.6 A tracking system for audit findings is established to help assure that all findings are appropriately addressed and to trend audit findings."

Compliance Response

Requirements of this acceptance subcriterion are satisfied on page 18-3 of the program, second paragraph, which states that, "Procedure QAP-18.1...

requires the QA Manager to maintain a tracking system to ensure that all audit findings and observations are promptly addressed." Further information is supplied in procedure QAP-18.1, Subsection 4.17, which states that, "The QA Manager shall maintain a tracking system for audit findings and audit observations to ensure that all audit findings/observations are properly addressed. The tracking system may be modeled on the NCR tracking log of procedure QAP-15.1 or the CAR tracking log of procedure QAP-16.1. Audit findings classified as nonconformances shall be tracked in accordance with procedures QAP-15.1 and QAP-16.1, as appropriate." See procedure QAP-18.1, Subsections 4.13 through 4.13.3, which addresses classification of audit results.

"18.7 The audited organization describes in a formal report the corrective action to be taken to address findings. This report is submitted to the auditing organization and/or responsible management."

Compliance Response

The intent of this acceptance subcriterion is responded to on page 18-2 of the program, fourth paragraph, which states that, "Procedure QAP-18.1 requires audit reports... signed by the QA Manager and distributed to the Responsible Individuals audited, and to the Executive Director... the Administrator of Technical Programs, and... others... The audit report includes a statement of any... audit observations, audit findings classified as nonconformances, and other audit findings. The Responsible Individual audited is required to submit a written response to the

audit to the QA Manager... (and)... the response must indicate corrective action... including implementation date... for audit findings and audit observations." "(Audit findings classified as nonconformances are processed per procedure QAP-15.1, 'Nonconformances' and procedure QAP-16.1, 'Corrective Action'...)" See procedure QAP-18.1, Subsections 4.13.2 through 4.14.2 which requires the Responsible Individual audited to confer with the QA Manager and others and to formulate a corrective action plan in a written response to the audit report (for audit observations and audit findings not classified as nonconformances). See response to Subcriterion 16.1 for documented corrective action response for audit findings classified as nonconformances.

"18.8 In the resolution of findings, the root cause of each finding is also identified and corrective action for it described."

Compliance Response

Concerning audit observations and audit findings not classified as nonconformances, this acceptance subcriterion is addressed on page 18-2 of the program, fourth paragraph, which states that, "The response... (to the audit report)... must include corrective action... including root cause determination..." With further reference to audit observations and audit findings not classified as nonconformances, procedure QAP-18.1 requires that corrective action plans must consider root causes (Subsection 4.14.2, last paragraph) and must be approved by the QA Manager (Subsection 4.14.1) who also verifies completion of

corrective action (Subsections 4.15 through 4.15.2). With respect to audit findings classified as nonconformances, to nonconformances detected by means other than audits, and to nonconformances classified as significant conditions adverse to quality, procedure QAP-16.1, "Corrective Action" specifies similar identification of root causes, appropriate corrective action, and verification of completion of corrective action (Subsections 4.3 through 4.5, 4.14 through 4.14.2, and 4.15 through 4.15.2).

Conclusions

The NWPO QA Program and implementing procedures comply, insofar as possible, with the "NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories," Appendix A, June 1984, and with other documents listed in the References section, herein. However, the program and procedures do not adhere to acceptance criteria that are not applicable to NWPO's objectives, intentions, strategy, or circumstances. The following acceptance criteria/subcriteria of the NRC review plan contain elements that NWPO has modified, interpreted, or not included in its program and implementing procedures. See the appropriate compliance response for explanations and details.

Criterion 1 - Subcriteria 1.1, 1.2, 1.3, 1.4, 1.7, 1.8, 1.9, 1.10, 1.11
Criterion 2- Subcriteria 2.1, 2.4, 2.5, 2.8
Criterion 3 - Subcriteria 3.1, 3.2, 3.5, 3.7, 3.10
Criterion 4 - Subcriteria 4.1, 4.2
Criterion 5 - Subcriteria 5.1, 5.2
Criterion 6 - Subcriterion 6.2
Criterion 7 - Subcriteria 7.1, 7.3, 7.4
Criterion 9 - All Subcriteria
Criterion 10 - Subcriteria 10.1, 10.2, 10.3
Criterion 11 - All Subcriteria
Criterion 14 - Subcriterion 14.1
Criterion 15 - Subcriterion 15.1
Criterion 16 - Subcriterion 16.2
Criterion 17 - Subcriterion 17.1
Criterion 18 - Subcriteria 18.1, 18.2, 18.7